ADDIS ABABA UNIVERSITY COLLEGE OF HEALTH SCIENCES

SCHOOL OF PUBLIC HEALTH

Assessing safety and ethical issues among participants in a herbal medicine phase I clinical trial: conducted in Addis Ababa Ethiopia: A Mixed Methods Research

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ADDIS ABABA, ETHIOPIA

I. TABLE OF CONTENTS

II.LIST OF TABLES

III.LIST OF FIGURS

IV.LIST OF ACRONYMS

ADR	Adverse Drug Reaction
AHRI	Armauer Hansen Research Institute
ALERT	All African Leprosy Rehabilitation and Training Center
CTD	Clinical Trial Directorate
CDT	Center for Innovative Drug Development and Therapeutic Trials
FDG	Focused Group Discussion
GCP	Good Clinical Practice
ICS	Informed Consent Sheet
IRB	Institutional Review Board
US	United States of America

V. ABSTRACT

Background: Ethics in the conduct of clinical research is mandatory to protect research participants. The goal of phase I clinical trial is to determine the maximum dose of the new medication that may be administered without the risk of serious side effects. Participants in most of phase I clinical trial have no direct benefit in participating in the trial but the amount of money provided for compensation can cause the participants to participate without being concerned to the risks the new drug may bring.

Objective: To investigate the safety and ethical issues among healthy volunteers in phases I clinical Study in Addis Ababa, Ethiopia in 2024.

Methods: An institutional-based cross-sectional study design mixed with a qualitative description approach was employed. The study was conducted at Armauer Hansen Research Institute; semi-structured interviews were conducted face-to-face. Data was entered into the Kobo toolbox and exported to SPSS version 24; a descriptive analysis was done; and the socio-demographic characteristics of the study participants were described. For qualitative method, twelve interviewees were purposefully selected and interviewed. An open-ended question was developed to facilitate in-depth interviews with respondents. Interviews were audio-recorded with consent. Transcriptions were entered into ATLAS.ti and coded. The data was analyzed using a thematic analysis approach.

Result: The major motivation of participants (54.4%) was financial benefit. The majority of the participants (52.6%) had a low monthly income of less than 2000 birr per month, followed by (42.1%) agreed to the need to help in the development of new drugs. When deciding to join a trial, the majority of them (40.4%), strongly agreed with giving consideration to the type of drug under investigation and the level of risk that can be caused. Altruism and medical care provided by the trial site were also the other major decision factors mentioned.

Conclusion: The findings of this study indicate that the motivations and enrollment decisions of healthy participants to engage in a phase I clinical trial are diverse, extending beyond financial incentives. By taking these factors into account, researchers can develop more effective approaches to engage and protect the healthy volunteers in the trial.

KEYWORD: Healthy volunteers, Motivation and decision factors, phase I trials.

1. Introduction

1.1. Background

According to the Belmont Report, there are three fundamental ethical principles for clinical research: beneficence /non-maleficence/, justice, and respect for people, which are the main guidelines that must be followed when conducting research involving humans (1). The ethics of healthy volunteer participation in clinical trials are complex and important issues. Phase I trials are often the first to include human subjects. It is done to test medical interventions, including therapeutic medicine, other cell and biological products, vaccines, surgical interventions, diagnostic procedures, devices, behavioral therapies, and other preventive interventions (2). The goal of phase I research is to determine the safest dose of the new medication that may be administered in humans without the risk of serious side effects. The treatment's adverse effects on humans cannot be determined with certainty, despite testing it in laboratories and in animals (3). The optimal technique to administer the new therapy is also determined by these trials.

Phase I trials are mostly done on adult participants who willingly take part in a drug trial where the exact risk is not well known (4). Unlike other phases of a clinical trial where participants participate for health benefits phase I clinical trials have no direct benefit for the participants. Participants in phase I trials commonly receive financial benefits for participating in a trial that may contribute to exploiting participants without giving much attention to the risk of the new treatment. The healthy volunteers will be constantly observed throughout the study through monitoring, laboratory investigation, and physical examination. Usually, the phase I clinical trial lasts a few weeks or months (5). Researchers will be able to assess whether a medication or treatment is safe enough to try on a larger population with the assistance of phase I clinical trial results. The medication or therapy will proceed to phase II clinical trials if it is determined to be safe (6). However, it is commonly a concern; experts fear that participants in the phase I clinical trial could be exploited because most could be from low socioeconomic and disadvantaged groups of the population. Nevertheless, such experiences of study participation by healthy volunteers are not systematically analyzed and known in Ethiopia. This study aims to review the

experience and describe the socio-demography, motivation, and decision factors considered by the phase I study participants in Ethiopia.

1.2 Statement of the problem

The need to protect the rights, safety, and dignity of research participants became more significant, and the development of basic ethical principles followed the historical malpractice of clinical trials on healthy participants, like in the Nazi experiment, the Tuskegee Syphilis study, and many other studies that were conducted on healthy human beings (9).

Nowadays, many infectious and non-infectious diseases are all over the world, and much more clinical research is being conducted and the development of new and effective medication development has increased through the years (10). The major issue in clinical trials involving healthy volunteers is that individuals volunteering on the phase I trial are of low socioeconomic status (4,8,9). Most participants in phase I studies are from disadvantaged populations, causing a proportional representation of the population in clinical trials that can potentially violate the concept of justice, one of the fundamental principles to be violated (10). Furthermore, since participants in the trial have no direct health benefit, the monetary reward they receive for taking part in a study may put them in a vulnerable position when deciding whether or not to participate.

On the other hand, healthy volunteers tend to participate in different trials conducted at different times, with some even considering it as sources of income. In developed countries like the US, UK, and France, volunteers tend to participate reputedly (8). This is the same for developing countries like Bangladesh (11) and South Africa (12), where volunteers search for trials as sources of income without considering the risk associated with the trial. The risk of repeated exposure of participants to different trials is not well studied. Incentives can cause them to overlook the risks of a trial. On the other hand, most volunteers in phase I trials are members of low-socioeconomic groups who are driven by rewards and willing to take risks but have restricted access to the medical products they help to develop (13).

The risks volunteers face could be life-threatening: the case of a 24-year-old previously healthy woman who died as a result of an asthma experiment done in the US (14), and also the trial in France, which caused six volunteers to be hospitalized and the death of one man (15). It is

critical to evaluate how healthy participants in phase I trials are motivated and how they decide to join a study in order to make an empirical contribution to longstanding ethical issues regarding healthy volunteers' involvement in drug research. Making an effort to understand the motivations, and perceptions of trial participants helps to protect them from ethical violations.

1.3 Significance and Rationale of the Study

The findings from this study will have a great contribution to further understanding participants' reasons for their enrollment and non-enrollment in research studies, the existence of therapeutic misconceptions, and the extent to which research participants are aware of their rights. And it could also help trainees advocate for support, persuading important stakeholders to change research policy. Such surveys will help to understand the barriers to the adoption of policies that promote ethical conduct in research at the national level. And it will also help decision-makers like the institutional review boards (IRB) when reviewing a trial proposal to determine whether the statement on informed consent about the risk and the financial amount doesn't influence participants.

Ethiopia has developed a road map to increase the number of clinical trials being conducted in Ethiopia, and issues or concerns about the protection of the healthy volunteers participating in a trial will become mandatory. The worry that financial incentives cause healthy volunteers to take on unwarranted risks shows that they are influenced. That being said, not much is known about the preferences of healthy participants or how they choose which studies to take part in.

2. Literature review

The key emphasis of the study is on the socio-demography, motivation, and perception of healthy volunteers in clinical trials. Accordingly, the review will look at the different perceptions and combinations of society that are participating in clinical trials, as well as the association with socio-demography suggested by different authors. Since Ethiopia is on the road to developing the number of clinical trials done, this study will help to protect the participants and to ethically conduct trials.

2.1. Socio-demographic characteristics

Phase I healthy volunteer clinical trials should be designed, with special attention to important demographic factors like age and sex, to include participants who can provide externally valid information about the safety and tolerability of novel therapies, which will ensure the translational science value (17). This will help the trials meet the ethical requirements.

The ethical concerns surrounding the recruitment of healthy volunteers for phase I clinical trials have been the subject of numerous studies recently. The primary concern with the healthy participants' involvement is the provision of informed consent, which is provided per various guidelines. For example, the Belmont report states that informed consent should not be subjected to undue influence or coercion (18). The various ways in which one can uphold the moral principles of informed consent may be affected by various factors. Among these, the age of the participant is one factor that will affect the comprehension level of the participants. In a study done in the US, 63% were between the ages of 30 and 49, 22.5% were between the ages of 18 and 29, and 15% were 50 or older, resulting in the participants' average age of 32 years (19,20). On the other hand, trial participants in China have a mean age of 28.5 ± 5.6 years (21). Similarly, a study done in South Africa shows that the mean age of the participants in the trial was 25 years (12). This may be because younger generations might not have as much financial experience and might be searching for additional sources of income (8).

The other factor affecting the comprehension level and exposing trial participants to undo influence and corrosion could be their socioeconomic status; the consent provided should be abided by the volunteers of the study participant, which is core for Healthy Volunteers. Socio-

economically disadvantaged groups often enroll in the majority of phase I trials. A study on the socio-demographic characteristics of healthy volunteers in the United States phase I clinical trial showed that of the participants, 25% worked full-time, 34% worked part-time, and 41% were retired or jobless and had yearly household earnings under $25,000. These individuals were discovered to be the majority of trial participants (19,22,23). Contrarily, given that this group is disproportionately underrepresented, they won't always be the first to profit from trials.

According to the study, racial and ethnic minority groups are the most likely to volunteer for phase I clinical trials but have the least access to trial results. Even in developed countries, the majority of the participants are from racial and ethnic minority groups. A study done in the US reflected that 40% of the participants were black American and non-Hispanic white (8). A similarly study done in Brazil and South Africa shows this (12,24).

Most of the studies recommend having literate participants who can understand the informed consent and can ask questions on the points that are confusing. A study done at the University of North Carolina shows that the majority of the participants had high school or some college (8). Contrary to this, approximately two-thirds of the participants in China had less than a high school education and were lower (21). Also, only about one-third of the sample from three regions in the US had a college degree (23).

Most trials conducted are guided to involve different population aspects, especially in terms of gender. In the United States, increasing the diversity of clinical trial participants has been a national public health priority since the early 1990s (25). Other phases of clinical trials may have a proportional number of participants, but in the case of the phase I clinical trial, the representation of female participants is very low. For instance, majority of the participants in phase I includes male; 74% of the participants in a study done in United States indicate males were the major participants (19,23). On the other hand, a comparative study done on Pfizer clinical trials in three different countries showed that Belgium had more than half of the participants females (56.6%) (9).

2.2. Motivation for enrollment

Enrollment incentives and time compensation are provided by monetary payments. (17) These payments can encourage the participants to take part in the trial without considering other risks, and a large amount of incentive for participation in a study with a greater risk could cause loss of trust from the public, which may also affect the reliability of the study outcome (26). To guarantee that a sufficiently diversified study group is enrolled, payment may be utilized as a means of encouraging greater involvement from individuals from various socioeconomic backgrounds (27). Among those who participate in healthy volunteer research, the majority are poor people, as seen in the majority of phase I trials in the US (19,28). Similarly, in Malawi, to prevent exploitation, research volunteers are compensated with a minimum of $10 for every study visit (29). A study in the US stated that most of the incentive is spent on investment, and the majority of the elderly participants preferred the free medical checkup as a motive more than the money (28). Contrary to that, the South African study attempted to demonstrate how research participants spent the incentive; most of them spent it to cover their basic costs of living, and the ideal reimbursement amount mentioned by participants ranged from 10 to 24 US dollars, which is consistent with the South African guidelines for reimbursement (12).

2.3. Enrollment decision

The Belmont report specifies participant benefit and risk minimization as research ethics' guiding principles (18); however, the phase I trial leaves much to be sought in terms of participant harm and direct benefit. Participants bear painful costs and minimized but unknown risks to assess the safety of novel medications. To minimize the risk of phase I trial, clinics should be designed and kept up to strict standards for participant wellbeing. Limitations on participant activities and the frequency and invasiveness of medical treatments should be kept to a minimum and supported by solid scientific evidence. The risks associated with research should be kept to a minimum, and participants' physical, mental, and emotional health should be supported at all times, not just while they are confined to an inpatient or residential facility (17).

Informed consent plays a great role in informing participants about the anticipated risk of the trial. A study done in Brazil showed every interviewee stated they had read and comprehended

the informed consent sheet (ICS). They also mentioned instances in which they had doubts about whether a professional could assist them. Nonetheless, several participants were unable to recall any of the information when asked to recall the main ideas of the ICS; of those who could recall portions of the ICS, none brought up the possible hazards associated with the research they enrolled in (24). However, a US investigation revealed that study participants were aware of the risk before they participated. Some serial participants had gotten so familiar with the consent of the phase I trial that they didn't worry about the risk; additionally, participants minimized the severity of harm by appreciating the researchers' attention to detail in guaranteeing their safety (22,30).

The other is the perception of participants for the adverse reaction. According to a comprehensive evaluation of the number of adverse events experienced by healthy volunteers, phase I trials do result in mild to moderate harm, but there is little chance of severe harm (13,31). Nowadays, there are lots of phase I trials being conducted, and participants are also participating in different trials as a source of income, as reported by phase I participants in South Africa (12). A study done in the US reported that can unduly influence participants with regard to adverse reactions and considering the ADR as insignificant because their bodily changes were not that significant. participants also perceived the ADR as imaginative and not happening in real situations, others tend to compare their ADR with that of other participants who had a more serious reaction and disregarded their reaction as insignificant (22).

2.4. Conceptual Framework

The conceptual framework is developed from different literatures, and it describes different variables that have relation to the contribution of the conduct of a safe phase I trial on healthy volunteers.

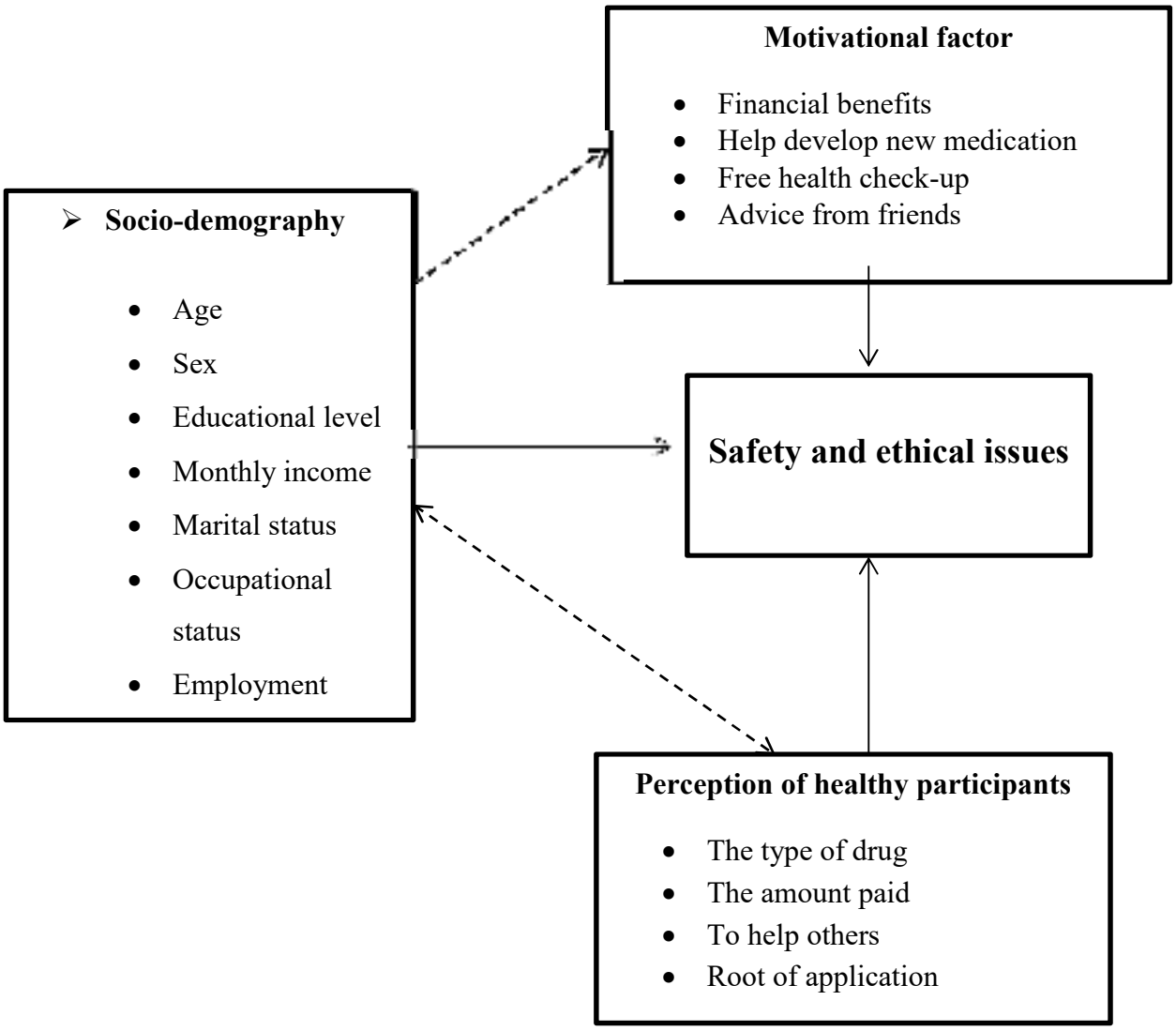

Figure 1 Conceptual framework on safety and ethical issues of participants on phase I clinical trial (4).

3. OBJECTIVE

3.1. General objective

- To investigate the safety and ethical issues of healthy volunteers on phase I clinical trial in Addis Ababa, Ethiopia, in 2024.

3.2 Specific objective

- To determine the socio-demographic pattern of phase I clinical trial participants in Addis Ababa, Ethiopia, in 2024.
- To determine motivational factors for phase I clinical trial participants in Addis Ababa, Ethiopia, in 2024.
- To explore the perception and process involved in deciding to take part in a phase I clinical trial in Addis Ababa, Ethiopia, in 2024.

4. MATERIALS AND METHODS

4.1. Study setting

The Armauer Hansen Research Institute was founded in 1970 through the initiative of the Norwegian and Swedish Save the Children organization, seconded by the Ministry of Health of Ethiopia. AHRI was established as a biomedical research institute located next to the all-African leprosy rehabilitation and training hospital (ALERT). The institution joined the Ethiopian Ministry of Health in 2004.

The Clinical Trial Directorate (CTD) has been conducting various drug, vaccine, and device trials since its first initiation of a good clinical practice (GCP) compliant clinical trial in 2001. The Directorate has four divisions: the drug trial division, the vaccine, diagnostics, and medical devices trial division, the bioequivalence (BE) and clinical pharmacology divisions, the trail management division, and the quality assurance division. Most of the trails done were mostly phase II and phase-three. CTD took the national initiative for the conduct of the first bioequivalence study in Ethiopia in collaboration with the regional bioequivalence center in Addis Ababa in 2014. Since then, ciprofloxacin and co-trimoxazole tablet bioequivalence studies have been conducted on healthy volunteers. The site had a pre-inspection experience with WHO auditors in 2015. Currently, the site is working on the WHO pre-qualification submission of a new pediatric formulation of primaquine. Another drug trail on herbal drugs for different skin fungal infections has been conducted on healthy volunteers. This herbal drug clinical trial is conducted on healthy volunteers to detect any reaction to patch and repeated open application on the healthy volunteer skin, which was conducted from November 10, 2023, to December 28, 2023 (32). AHRI at the moment of the study had 200 healthy volunteers registered.

4.2. Study design

An institutional based quantitative cross-sectional study method mixed with a explanatory qualitative research approach was implemented, which is used to understand the motivation, deciding factor to join the phase I trial, and the perspectives of the people involved in the trial. The data was gathered from healthy individuals who took part in the herbal drug phase I trial in order to address research problems.

4.3. Source and Study Population

All healthy participants registered on the volunteer pool database were the source population, and the study populations were those who have participated in phase I clinical trial conducted in AHRI on herbal drug trials. Safe Herb is a drug safety trial conducted to detect any reaction to patch and repeated open application on the healthy volunteer skin, which was conducted from November 10, 2023, to December 28, 2023,

Healthy volunteers who had provided consent and passed screening test were included in the study, and those who had not provided consent but were registered as volunteers were excluded from the study. Participants were selected from the volunteer screening log and were contacted by phone if they want to participate in the study.

4.4. Sample Size Determination

Sample size for quantitative study was determined using single population proportion formula for three different variables (Age, satisfaction for rewarded, Attitude about competency of investigators). The assumptions made to calculate the sample size are proportion from previous study done (4). Margin of error taken to be 5%, 95 % confidence level ($Z\alpha/2$= 1.96) and estimated non response rate of 10% was considered and then the largest sample size was taken which is 80. Then by using the correction formula because the population size is less than 10,000, final sample size will be 57, by using the following formulas:

$$n = \frac{(Z\alpha/2)^2 \ (P\ (1-P)}{d^2}$$

$$n = \frac{n^o}{1+ ((n^o-1)/N)} = 57.34 \approx 57$$

Table 1. Sample size calculation

Variables	Proportion (P)	Confidence level (Zα/2)	10% non-response rate	Margin of error (d^2)	Total sample size
Age	0.02	95%	3	0.05	33
satisfaction for rewarded	0.047	95%	11	0.05	80
Attitude about competency of investigators	0.007	95%	2	0.05	12

The sample size for the qualitative study was determined by selecting healthy volunteers who participated in the phase I trial that was conducted. The total sample size for the qualitative was determined when saturation was attained. Monitoring of the data as it is being collected and analyzed was done to paying attention to the emergence of new themes and the frequency with which they appear and saturation was reached when the information being gathered is repeated and redundancy of data starts to occurred.

4.5. Sampling procedures

For the quantitative study, participants were selected by using simple random sampling from the screening registration log. And for the qualitative participants, they were recruited by using the purposeful sampling technique among which homogeneous sampling was used to select individuals with similar demographic or social characteristics.

4.6. Data collection procedure

Data for quantitative study was collected using semi-structured interviewer administered questionnaire that is developed from different literatures (4,9). The questionnaire was prepared in English and then translated to Amharic, The questionnaire consists of two parts; first part contains questions on socio-demographic information and section two on motivation and perception of volunteers on clinical trial. Independent variables of socio-demographic data like (age, sex, educational level, monthly income, marital status, occupational status, employment status) and experience and perception of clinical trial was used to answer the research question.

The interviewer provided the consent prior to the interview in a private area to insure privacy. The consent could be verbal for those participants were the interview was conducted by phone call and written for those who came in-person, if the participant expresses their willingness to participate, the interview proceeded. An in-depth interview was conducted with the healthy volunteers for the qualitative. The interview guide was prepared in English and translated to the Amharic language. The interviews were tape-recorded with the participants' permission and field notes were been taken by the interviewer during the interview. The interviews were carried out in places where silent and secure for study participants. Interviewers interviewed participants by using open-ended semi-structured questions and were interviewed for 20 to 30 minutes, by probing questions in turn to ensure information saturation.

The Independent variables in the study include; in the Socio-demography includes Age, Sex, Educational level, Monthly income, marital status, Occupational status, Employment status, Housing condition and perception of the participant about the risk and their experience in the trial.

Training was given for data collectors who were health professionals having experience in collecting qualitative interviews, and on method of extracting the pertinent data through interview and on how to keep notes and on how to complete questionnaires.

4.7. Operational definition

Clinical trial: A clinical trial is a systematic process that is intended to find out the safety and efficacy of a drug or device in treating, preventing or diagnosing a disease or a medical condition(33).

Phase I clinical trial: Are the first stage of testing in human subjects, normally, a small group of healthy volunteers will be selected. It is designed to assess the safety, pharmacovigilance, tolerability, pharmacokinetics, and pharmacodynamics of a drug (34).

Safety of the study: It is the feeling of being protected from external threats, risk, or dangers. Perceptions of insecurity influence subjective well-being because insecurity implies a lack of control or autonomy of the individual in relation to managing his environment (35).

Screening Log: A log use to list out potential participants for a study after they have provided consent and for the screening tests to be performed (36).

The type of drug in clinical trial: there are several types of drugs that are being tested and put to the market for this study the type of drug is indicating the herbal drug produced locally and of those modern drugs.

Undue influence: Influence by which a person is induced to act otherwise than by their own free will or without adequate attention to the consequences (37).

Coercion: The Practice of persuading someone to do something by using force or threats (37).

Risk in clinical trial: Potential for harm, it is a prediction of a probable outcome based on evidence from previous experience

4.8. Data Management

Data was collected and was entered to the designed Kobo plate form; entered data was verified and reviewed to identify and correct any error and inconsistency. Data was stored securely and in an organized manner, data was regularly backed up to prevent loss in case of system failure. Data was cleaned by checking the missing values and decide how to handle, identify and delete any duplicated file, correcting inconsistences, identification and assessing outliers and decide whether to delete transform or correct it. And also to ensure data types are appropriate for each variable merge or split categories were used as needed and standardizing unit of measurement, checking the distribution of the variable to identify unexpected pattern then performed post cleaning checks. SPSS version 24 was used to analyses the data.

For the qualitative data all the audio records was backed up after every interview on to a secured file, data was entered on ATLAS.ti version 9, categories were clearly defined and coding was developed to organize the different aspects of the data, contextual information was also captured and used for analysis. Data was cleaned by checking the accuracy of transcription by listening to the records. Any personal data was removed to keep confidentiality. Redundant information was removed and off topic information that does not contribute to the research question were excluded.

4.9. Data Analysis Procedures

Descriptive analysis was used to describe the socio demographic characteristics of the study participants and other variable in the study. The mean for the Likert scale variables was calculated by using descriptive analysis for comparing the five scales. The mean value range for strongly disagree (1.0-1.80), Disagree (1.81-2.60), Neutral (2.61-3.40), Agree (3.41-4.20), strongly Agree (4.21-5.0) and the mean was interpreted based on the value range. Information in the audio recorders and field notes was stored in a separate file as soon as each interview is wrapped up. All audio records were transcribed verbatim and translated into English. The transcripts and translations were cross-checked for consistency. Translated notes were read and re-read to define categories and sub-categories guided by the objective of the study. Then a codebook was prepared. Thematic analysis was carried out using ATLAS.ti version 9 to code the transcripts based on the codebook. Thematic analysis approach was used by first familiarizing to the data and them coding and gathering themes, reviewing the themes then write up.

4.10 Data quality assurance

4.10.1 Data quality assurance for quantitative

Translation of questionnaire from English to Amharic and back to English, one expert working on participant recruitment at AHRI were asked to complete the questionnaire to cheek the consistency between the Amharic and English version. Supervisors ensured that all data was complete and if any data was missed the participants were contacted by phone and data was completed.

Pretest was done before actual data collection is started on healthy volunteers who have participated on previous phase I study conducted in AHRI. And important adjustments were done on the questionnaire for internal consistency.

4.10.2 Trustworthiness for qualitative

4.10.3 Credibility

Some data were collected by the investigator to help observe the actual context of data collection, as stated by Guba, to ensure credibility (38). Triangulation of data using different sources of information from those who have been enrolled and those who were just consented but not enrolled, and also data was collected from both male and female healthy volunteers, participating in phase I studies. There was peer debriefing with advisors; interpretations of responses were done by preparing a codebook and labeling codes according in to different themes; and conclusions were drawn from the raw data using direct quotes to elaborate on the codes and categories.

4.10.4 Transferability

A thorough description of the research context, study setting, and participants was kept by note. For other researchers to be able to assess whether or not the research findings are transferable to other contexts, additionally, contextualization and a clear articulation of the distinctive contextual factors that may have influenced the research findings was discussed with the interviewers.

4.10.5 Dependability and Conformability

To enhance dependability regular discussions and debriefing sessions was conducted with experts in the field; experts are principal investigators at AHRI working on phase I trial and with advisors at AAU. To insure dependability of the research outcome by maintaining the degree of consistency, stability, and reliability of findings and interpretations during the research process is referred to as dependability (38), conformability is established during data collection and analysis by maintaining the participant viewpoints and experiences rather than the researcher's own prejudices or skewed interpretations.

To establish conformability, the research process, decisions made, data collected, analysis procedures, and any modifications or adjustments were recorded. With the use of this documentation, accountability and transparency were enhanced, enabling outside examination and validation of the study procedure. The process of analysis was validated by comparing the preliminary category with the text quotes.

4.11 ETHICAL CONSIDERATION

Ethical approval was obtained from the Institutional Review Committee of the school of public health of Addis Ababa University and AHRI. Written or oral consent was obtained from every participant before the interview by explaining the objective of the research. All the information collected from the study participants was handled confidentially by omitting their identification, conducting the interview in a private place. Data was used for the research purpose only. Selection of participants was applied by including different aspects of the population.

5. RESULT

5.1. Socio-demographic characteristics

In this study, a total of 57 healthy volunteers were included. The age of the healthy volunteers was not normally distributed. The median age is 33, with an interquartile range of 18- 49. The majority of respondents were under the age of 45. Among the respondents, 30(52.6%) were male; more than 46(80.7%) of the volunteers have fulltime jobs. Concerning their educational status, 25(43.9%) of the respondents have the highest level of education. The majority of the respondents 30(52.6%), had an income level of less than 2000 birr per month. The majority of the respondents 48(84.2%) were their first time to participate on a phase I trial.

Table 2: Socio-demographic characteristics of healthy volunteers participating on phase I clinical trial in Addis Ababa 2024, (n=57).

variables		**frequency**	**Percent %**
Median, IQR of age 33, (18-49)			
Age	18-30	24	42.1
	31-45	31	54.4
	>45	2	3.5
Sex	Male	30	52.6
	Female	27	47.4
Marital status	Single	16	28.1
	Married	38	66.7
	Divorced/ Widowed	3	5.3
Occupational status	Student	4	7.0
	Full time	46	80.7
	Part time	4	7.0
	Unemployed	3	5.3
Educational status	Can read and write	1	1.8
	Primary	11	19.3
	Secondary	20	35.1
	Tertiary and above	25	43.9
Monthly income	<2000	30	52.6
	2000-5000	18	31.6
	>5000	9	15.8
Housing condition	Family-owned	16	28.1

	My own house	10	17.5
	Rent house	31	54.4
Current type of residence	With family	17	29.8
	As a head of the family	33	57.9
	Alone	7	12.3
Number of clinical trial participated on	One	48	84.2
	Two	6	10.5
	Three and more	3	5.3

5.2. Motivational factor for healthy volunteers

The majority of the volunteers 31(54.4%) strongly agreed that they were motivated by the financial benefit they receive from participating in phase I trials. But the motivational factors are multiple and not only limited to one factor; other motivational factors, like being able to contribute to the development of new drugs, constitute about 24(42.1%) of the factors for motivation among participants. About 29(50.9%) of the volunteers were not curious to know about clinical trial.

Table 3: Motivational factor for healthy volunteer participating in phase I trial Addis Ababa, Ethiopia (n=57).

Name of variable and classification	**SD N (%)**	**DA N (%)**	**N N (%)**	**A N (%)**	**SA N (%)**	**Mean value**
Contribute to making a progress of medicine by discovering new knowledge	2(3.5)	12(21.1)	7(12.3)	24(42.1)	12(21.1)	3.56
Chance to have a free health check-up	5(8.8)	22(38.6)	4(7.0)	14(24.6)	12(21.1)	3.11
Curiosity about clinical trials	15(26.3)	29(50.9)	3(5.3)	7(12.3)	3(5.3)	2.19
Receive financial reward for participation	1(1.8)	5(8.8)	3(5.3)	17(29.8)	31(54.4)	4.26
Advice from family/friend	4(7.1)	39(69.6)	1(1.8)	12(21.4)	0(0)	2.38

NB: SD-Strongly disagrees DA-disagree N-neutral A-agree SA- strongly agree

5.3. Enrollment decision of healthy volunteers

The majority of participants, 23(40.4%), decided to participate in a phase I trial based on the drug type that was being tested. And also, 41(71.9%) of the participants decided to take part in a phase I trial due to the presence of medical care in the clinical trial. While 28(49.1%) of the main factor is altruism, or helping future patients.

Table 4: Enrollment decision of healthy participants in phase I trial Addis Ababa, Ethiopia (n=57).

Name of variable and classification	**SD N (%)**	**DA N (%)**	**N N (%)**	**A N (%)**	**SA N (%)**	**Mean value**
Risk in health from adverse events to investigational drugs	0(0)	22(38.6)	7(12.3)	17(29.8)	11(19.3)	3.30
Length of participating period in clinical trial	9(15.8)	41(71.9)	0(0)	5(8.8)	1(1.8)	2.07
Frequency and type of procedures and examination in clinical trial	12(21.1)	41(71.9)	1(1.8)	2(3.5)	1(1.8)	1.93
Loss of income to be acquired unless you participate in clinical trial	10(17.5)	31(54.4)	1(1.8)	11(19.3)	4(7.0)	2.44
The type of drug being tested	1(1.8)	12(21.1)	2(3.5)	19(33.3)	23(40.4)	3.89
The time it takes for the procedure	4(7.0)	43(75.4)	1(1.8)	6(10.5)	3(5.3)	2.32
For helping future patients	1(1.8)	13(22.8)	1(1.8)	28(49.1)	14(24.6)	3.72
The presence of medical care at the CRO	11(19.3)	2(3.5)	0(0)	41(71.9)	3(5.3)	3.63

NB: SD-Strongly disagrees DA-disagree N-neutral A-agree SA- strongly agree

5.4. The reason to choose this particular herbal drug phase I trial over other study

Majority participants 35(61.4%) agreed that they choose this particular phase I study because the tested drug was prepared mostly from herbs. While 27(47.4%) were because it had a better payment for participation. And also, 18(31.6%) was due to the root of the application of the drug.

Table 5: the particular study chosen to participate on phase I trial Addis Ababa, Ethiopia (n=57).

Name of variable and classification	SD N (%)	DA N (%)	A N (%)	SA N (%)	Mean value
Herbal drug	2(3.5)	9(15.2)	11(19.3)	35(61.4)	3.39
Particular study/Procedure	14(25.0)	27(48.2)	12(21.4)	3(5.4)	2.07
Better Payment	1(1.8)	9(15.2)	20(35.1)	27(47.4)	3.28
Root of application	6(10.5)	19(33.3)	18(31.6)	14(24.6)	2.70

NB: SD-Strongly disagrees DA-disagree N-neutral A-agree SA- strongly agree

5.5. Experiences and perception of healthy volunteers

The majority of the participants 44(77.2 %) believed that the study was a low risk study and that 50(87.2%) of them believed that they were safe during the study. And the majority of them 39(68.4%) said that they would participate in similar type of studies in the future.

Table 6: Experiences and perception of healthy volunteers on phase I trial Addis Ababa, Ethiopia (n=57).

Experience and Perception of healthy volunteers		N	%
Would you participate in the trial even though you didn't receive any financial reward	Yes I would	33	57.9
	I am not sure	20	35.1
	No I would not	4	7.0
The way of acquiring information about the trial from staff of the hospital or clinical trial from former participants	Though the poster and notification	18	31.6
	From staff of the hospital or clinical trial From	15	26.3
	Former participants	24	42.1
Before participating did you ask someone else opinion about your participation	Yes	24	42.1
	No	33	57.9
Whom did you ask opinion about your participation	Family member/partner	15	26.3
	Fiend	7	12.3
	Health professional	2	3.5
Did people recommend you to participate or not	yes	8	14.0
	No	16	28.1

If they recommended you not to participate what was their reason?	Risk of clinical trial	16	28.1
	Perception of genie pig	0	0
If they recommended you not to participate did they have any experience participating in a clinical trial before?	Yes	1	1.8
	No	22	38.6
How do you consider the final reward in the clinical trial you participated	Satisfactory	15	26.3
	Reasonable	9	15.8
	Unsatisfactory	32	56.1
Was your actual experience in this trial different from the information provided before your participation for consent	Yes	5	8.8
	No	52	91.2
How did you fill about the occurrence of serious complication during the trial	I never feel that possibility	19	33.3
	Occasionally I feel that possibility	35	61.4
	I feel that possibility all the time	2	3.5
Would you participate on a healthy volunteer clinical trial again?	Yes	39	68.4
	No	11	19.3
	Not sure	7	12.3
Did you think your safe in this trial	Yes	50	87.7
	No	7	12.3
Can you rate the amount of risk of this study	Low	44	77.2
	Medium	8	14.0
	High	5	8.8

5.6. Qualitative interview result

Based on this study, six main teams were identified, which were: participant impressions on phase I trials, means of motivation of healthy volunteers, what factors participants consider during the decision making to take part in the study, perceived disadvantages, barriers for healthy volunteers, and perceived community response.

5.6.1 Participant awareness on phase I trial

Awareness about clinical trial

Participants assume that clinical trials will be done on patients, and a male participant in his late twenties hesitated to volunteer for the trial because he was terrified after hearing that a trial was

conducted on healthy individuals. The one thing he was most worried about was the side effects. He explained saying:

"I assumed every experiment will be tested or check on unhealthy individuals……I hesitated just a little bit……. because of the side effects" (IDI: Male 28yr)

Another participant mentioned that she never heard of a clinical trial and was aware of it after the information provided during the consent.

"……..I don't have that much information until i came hear and was given information……."(IDI:Male 28yr)

Most of the volunteers had no information about what phase I clinical trial is except those who had participated previously, and those with a health background also had a better understanding of what phase I trial is. For example, a nurse working on the MDR ward explained what a clinical trial is and how it is conducted precisely.

"when we start from the definition of clinical trial, it is applying new medicine on people or animal's, whether healthy or sick individuals. If you conducted an experiment on a sick individuals it could lead to a complications, so I believe it is a right thing to try on a healthy individuals" (IDI: Male 29yr)

5.6.2 Motivational factors

Financial motivation

According to the key informants, the main motive of healthy participants is multiple, but most of the participants mentioned financial benefit as the most important factor. Some mentioned that hearing rumors about the possibility of an incentive for participation led the participant to join the study despite initially losing interest. This was primarily because they believed the incentive might alleviate some of their financial difficulties. Others also argued that the main benefit of the study goes to the pharmaceutical company, and the only benefit they get is the financial reward.

"*It's been a long time since I have heard about the study, but I wasn't interested to participate, but when my friends came here I came along with them. To tell you the truth, I heard when they talked that it has an incentive, ……since I had my own reason ……like*

shortage of money and many other problems (looking down on the ground) I decided to register" (IDI: Male 29yr)

Most of the participants mentioned other motives, like the use of the drug for future patients, are also motivations for healthy volunteers. Since the drug tested is used in the treatment of fungal infections, participants related the problem as very important and needed a solution, like the people close to them. A female participant mentioned that her daughter has a fungal skin infection that reoccurs repeatedly, so she thought if she sacrificed herself for the drug to be tested on her, if it was effective, it would benefit her daughter.

"Although my daughter has fungus on her skin, so I wanted to see if the medicine has a solution for that, after it tested on me (Smile)" (IDI: Female 35yr)

On the other hand, a male participant said that he had no intention of scrifing himself for the better outcome of the drug for future patients; he said he just wanted to know his health status from the tests done for screening purposes.

"……. Also I wanted to check my skin tolerance. I assumed my skin was sensitive to sunlight" (IDI:Male 35 yr)

Most participants encouraged their friends or family members back home to take part in the trial, but the majority of them declined. Some even got into arguments and were questioned about why they would do such a thing to themselves. When a female participant encouraged her sister to take part in the study, the sister became furious. Why would she put herself in danger for a study like this?

"……specially my sister she was extremely mad at me. She said "What makes you sure this drugs are safe…… how do you know that?" (IDI: Female 24 yr)

Others argued that the amount of incentive provided was not that attractive to motivate them to participate. A participant suggested having an incentive for the possible occurrence of a side effect, and in spite of the presence of insurance for a side effect, he considered the incentive for the emotional support needed.

".....no not like that, am just saying if one of the side effect appears we would be morally discouraged, we have been informed that we have a health insurance when ever a side effect occure, but, in addition to that an incentives for our moral also....." (IDI: Male 28yr)

Altruism

The other aspect is that the main reason for deciding to participate in a phase I trial is for the purpose of helping future patients who will benefit from the drug production. A female participant in her late thirties even thought that if she got the disease in the future, she might use the drug and benefit.

"……because if it succeeded it would be great, because even if I get the same disease in the long run I would use the medicine for myself or other as well"(IDI: Female 38yr)

Others believe that the benefit not only goes to them and their close ones but also to the nation in general because drugs exported from developed countries are expensive and not easily accessible. A male participant in his late twenties said such traditional medicine development is important for the nation as a whole.

"……instead of importing medicine from foreign countries its better to manufacture here by using our own traditional medicines, because our current situation is very much tight regarding foreign currency and to save foreign currency as well" (IDI: Male 29yr)

participant in his forties who had participated in a trial more than three times explained that the main reason for deciding to take part in the study was because he believed that his participation would benefit society and that it was similar to donating blood to save lives.

"I assume that participating in this study is similar with donating blood, when donating blood it is to help peoples who need it.....so participating on this study is also similar to that of donating blood……. both are helping the society, that is why I sacrificed myself" (IDI: Male 41yr)

Health status

The medical screening done at the beginning of the study is beneficial to prevent the occurrence of adverse events, because if the participant is fully healthy, the effect of the drug may not be

that great and the risk of the drug will be minimal. Female participant who regrets suggesting her friends to participate, but the one thing that made her sure was the presence of the first screening test done that will screen out the unhealthy individuals.

"But the good thing is, there is this screening before applying the ointment, Ahhhhhhh, this diagnosis requested to screen out their skin and blood, those who has a skin problem will be disqualified their blood also been checked as well, some of my friends found ineligible to the study, but the physicians have prescribed medication for those who have problems on their skin, some of them just came for one day and rejected, however they said, " it is good for us to know our health status even if we don't participate. And they were happy that they were able to know their health status" (IDI: Female 35yr)

Trust in one's own health condition because of past experience. A male participant was talking about how dependable his immune system was and the fact that he never surrendered to disease. He added that even if any adverse event occurred, his body could handle it.

"I don't bother much on this kind of things even if something happens I believe that I will be cured fast….i don't get sick that easily and even if I get sick I mostly don't get beat up that much easily ….i even go to work most of the time…… That's the reason why I participated even if peoples around me are saying lots of things ……..because i know myself (my body)…." (IDI: Male 29yr)

5.6.3 Consideration during decision to take part in the study

Type of drug

Traditional herbs are most frequently used by society. The majority of the participants considered the type of drug and how it was formulated when deciding to join the study. A participant who has participated in different studies mentioned that he was originally from the rural part of the country, and the herbs used to make these new drugs are used by society most frequently, so the familiarity of the test drug made him participate without worrying too much about the side effects.

"I grew up in the rural part of the country we have consumed these products (like "tosign".....) all my life I know it would not have that much of risk....." (IDI: Male 41yr)

One participant stated that his initial interest in taking part was sparked by his experience with the herbal medication in addition to a friend's recommendation. However, when he discussed the drug with his friend, who accompanied him, he expressed concern about any potential side effects and believed the additive substance to be more harmful than the herbs used to make the drug.

"Actually I used to think like him before, what if there was a hidden stuffs that they wouldn't want us to know, they hide that just to convince us to participate., but I have seen every step on the process nothing was new or untold" (IDI: Male 31yr)

A male participant also mentioned that this is a highly risky study because, even though the drugs are familiar, the chemicals that are added make them dangerous.

"if it has risk like this study..... I would not participate….since this herbs are known I decided to join…..but the chemicals used to make the drug may cause the side effect so it was hard to decide" (IDI:Male 35 yr)

The precense of medical care any time a side effect occure

The participant relied on the medical coverege that is provided by the trial institution, and even though the probability of risk occurrence was told to him on the consent, the provision of medical care if any adverse event occurs was one thing that helped him decide to participate.

"ya emm… as I have told you before (with loud voice) I have nothing to fear, because I believe even if something happened to me, the institution is able to cover full medical costs" (IDI: Male 29yr)

However, another participant stated that he did not rely on the medical care given because it might not be sufficient for a full recovery. He even used the example of an acid spill on the skin. The damage is permanent, and the only treatment available is supportive and preventive. He expressed concern that if any adverse reactions result in side effects, the extent of the medical coverage may not be entirely curative.

"Even if I encountered any side effects I would have full medical care, by the way the medical care could not make you fully guaranteed, because its similar with pouring acid on my skin and trying to cover my treatment expenses" (IDI:Male 35 yr)

Scientifically proven drug

The preparation of this herbal drug involves following the procedures used to produce a modern drug. A male participant argued that the drug was first tested on different experimental animals before being tested on humans, so she thought the drug would have fewer side effects.

> *"I believe that before the drugs would not be tested on us first, there are animals that have similar genetic make up and it will be tested on them first. Like rats and other animals, so the medications passes through all this phases before trial, before it come to us, I know this when I was in medical school. Even when it is applied on humans it only has a reaction, that doesn't direct harm that much, that how I convinced myself" (IDI: Male 31yr)*

A female participant mentioned that even she uses the herbs without knowing their exact dosing and that they use over-the-counter drugs without checking out the expiration date. But this is a scientifically proven product for which the doses are determined and would not cause harm.

> *"I mean, This herbs were scientifically checked and proven before it came here, we even buy medicine from open market without any prescription,for example there are such kinds of trends were if someone advises you to buy any drugs from pharmacy we would buy, let alone a medication that passed through research and many experiments"*

5.6.4 Perceived disadvantage

Negative consequences

Every time the medication was administered to the participants' hands or backs, the treatments caused them discomfort. The participant said he stepped outside of his comfort zone; he couldn't sleep at night because of the high temperature and worried about what people at work would think if they saw the adhesive on his back. However, because the drug application was only for a short while, he told himself it wouldn't be an issue.

> *"Yaa… especially during sleep time you become more cautious, so due to that you cannot sleep well, because during sleep time it's difficult to be cautious about the way you sleep. There are times that I couldn't sleep until the end of the study. In addition to that, I used to sleep shirt less all the time before the study, and wearing shi rt during sleep time was uncomfortable for me..... but It was just for short period of time so....."(IDI: Male 29yr)*

Possible side effect of the drug

On the first day after drug application, a male participant who lived with his sister and her small children was afraid for the children in the house because he felt uneasy and worried that something untoward would happen and that it might be contagious.

> *"I felt bad, but not scared, I wasn't scared for myself, my be if it was contagious, there are my sisters children in the house, so that made me uncomfortable....." IDI:Male 29yr*

Out of all the procedures carried out during the trial, the majority of participants were afraid of the part where the drug's reaction to sunlight was examined. This required shining direct sunlight on the drug-applied area. The participants became anxious at the notion of this step. They were concerned about any uncomfortable side effects or interactions between the medication and sunlight. Even though the participants were reassured by the safety precautions in place, they were nevertheless somewhat anxious about the test itself. They voiced worries about how the medicine would affect their skin's sensitivity to sunlight and its intensity.

> *"but the exposure to the ray was a bit intimidating. We were told we'd be under the sun for 30 minutes, which made me nervous. When we were actually there, the powerful light was unsettling. After that step, I felt panicked, wondering what would happen next. It was the only part that scared all of us. Other participants voiced their fear, questioning if they could handle it. Even though I knew it was safe, I still felt terrified" (IDI: Female 34yr)*

Time inconvenience

The participant noted that his hectic work schedule made the trial time schedule difficult for him and that he occasionally had to argue with his boss over being late to work.

> *"yes.. because I was always worried to get there on time , plus I work in trauma department and patients expect you to be there on time, and you get in a fight with your boss because of that, we have to stay here till it fully been absorbed.. to prevent contact with your clothes and the adhesion might get removed again, this stuffs makes you uncomfortable" (IDI: Male 28yr)*

The trial work schedule also caused difficulties for participants who traveled from far-off areas; one participant even said that the frequent trips were inconveniencing for him and that he had considered giving up on the study.

> *"time .....I had to work on Saturdays and I couldn't come that was the most inconvenient thing for my during the study, additionally, coming here frequently or daily makes it difficult even if you have to go somewhere else its impossible. It was difficult for me I almost quitted, however once am in I wanted to see the last part" (IDI: Male 35yr)*

5.6.5 Barriers for healthy volunteers

Root of application of the drug

Since external application carries a lower risk than oral or injectable administration, most participants opt for externally applied medications over these other forms of administration, which are perceived as far more dangerous.

> *"the problem would be, most of them said as long as it is an ointment that would be applied on our skin, we are ok with it, but not as a tablet or injection" (IDI: Female 35yr)*

Another concern is that the participant might not be able to identify and report an adverse occurrence in a timely manner due to the application being on her back.

> *"Ya—emm— she said to me there is going to be applied on my back and the other on my hand, what worried me a lot was the one on my back, because I am unable to see it clearly and its difficult to observe regularly, when it is applied on my back I was terrified what if something occurs on my back" (IDI: Female 30yr)*

Comunication of Final Result

The participant expressed disappointment over not receiving any communication regarding post-trial results. Almost all participants were waiting for the final result of the trial. A male participant expected a certificate for participation in the trial.

> *"yes……it's been 2 month since then…… we are still expecting. By the way there is one other thing left, as long as we participated in this study no matter what..... we should be appreciated (like certificate or.....)…. Because I believe this is a big research to save life, so*

anybody who is part of this study should be acknowledged, I believe only the researchers going to be applaud (benefited)" IDI:Male 29yr).

5.6.6 Perceived community response

Societal discrimination

People said they were greedy for participating in this study because they thought they were putting themselves in danger just for the money purpose. One participant mentioned that he was addressed as a greedy person for participating in such study.

"…….but there were many people who told me that I am a greedy person for participating in the study" (IDI: Male 29yr)

A female participant said that she kept on participating in the study secretly because she was afraid of the comments her friends and co-workers would give.

"he said if anything happened that up to you , I don't care " lough ", otherwise I haven't told to anybody…because I was scared of their opinion, If something happened to me they would say she done that for the money" (IDI: Female 30yr)

A female participant mentioned that there was a rumor at work that allowing oneself to be part of the study was believed to be part of an experimental study similar to that conducted on laboratory animals.

"the rumor was, some of our friends says we were like rats or sheep's lab animals in general I think they lack awareness about such kind of study. They make you panicked when you listen to them, if you involve in this…….something will happen to you they discourage you a lot due to lack of awareness" (IDI: Female 38yr)

6. DISCUSSION

A total of 57 questionnaire based interviews for quantitative study and twelve in-depth interviews for qualitative study were conducted with healthy volunteers who participated in a phase I trial, which is the first phase I trial to test a drug prepared from herbs in Ethiopia. Our study was conducted to investigate the socio-demographic characteristics, experience, perception (knowledge), motivations, and barriers among healthy adult volunteers participating in the phase I study.

In the study, the majority of the participants were male 30(52.6%) in comparison to other studies done in the US in which majority of the participants were males (19,23), in our study, the ratio was relatively comparable; this may be due to what the participants have mentioned: the familiarity of the drug. and also that, 77.2% of the participants thought the study was a low-risk study. The age of the majority of participants was in the range of 31 -45 with a median of 33 years, and an IQR of 18-49 which is similar to volunteers in the US, whose mean age was 32 years (19,20) and on the contrary, participants in China and Korea were young (4,39) and also South Africa (12).

Most of the volunteers in the study had a low income but had full-time work. A total of 52.6% of the participants had a low monthly income of less than 2000 birr per month, which is similar to the study done in China, where 58.8% had a low income (40), and in the US, were the majority of income is less than 2000$ (19). The majority 80.7% of the participants had a full-time job. Participants responded that since the amount of the income is not that much satisfactory, they need other sources of income to support their families. Most of the participants, 43.9%, had high school and college degrees, which is similar to the study in northern Carolina, where participants had high school or some college degree (8). On the other hand, studies in China and the US show that two thirds and one third, respectively, had college degrees. This may be attributed to the study's location, as the compound where the research is conducted is situated within a hospital complex, leading the majority of the participants to be educated. This is significant because it indicates that participants can read and understand the consent properly, helping to avoid any ethical issues. The majority of participants (84.2%) had never participated in a clinical trial in the past. But a study done in China showed that the majority (72.8%) of participants had previous clinical research experience (39). Similarly, in a study conducted in Korea, 64.2% participated in

the trial study (4). This difference may be due to the reason that Ethiopia is just on the way to developing the number of clinical trials, there are not many trials.

The majority of respondents indicated that motivation encompasses multiple factors and is not solely confined to a single motivation. And in this study, the majority of participants, 31 (54.4%), strongly agreed with a mean of 4.26 that their primary motivation was the presence of financial benefit, followed by 24 (42.1%) who agreed with the contribution to the future development of new drugs with a mean of 3.56. This is similar with a study done in Netherlands, mentioned that the largest group of volunteers felt that contributing to science and to research benefitting developing countries was an important motivation (41). And also, a study done in Tanzania on herbal remedies were participants major intention for motivation was altruism (42) and also the participants were motivated by the incentive provided on this study as majority of study determine that financial motivation as major factor (4,39). This can be explained by the low socio-economic status of the participants. Altruism could be the believe respondents have that the production of an effective and safe drug or the benefit of future patients and even themselves in the future.

The majority of respondents 32(56.1%) were unsatisfied by the incentive provided even though some have said they have used it for certain things, but the amount is not that interesting to go through all the trouble. On the contrary, in Korea, 94.1% of them were satisfied with the study (4). This is due to the growing inflation in the country, and the amount provided was lower as compared to that in Korea. For the study, where participants with low socioeconomic status are the major participants, caution must be taken with regards to the consent and risk information provided.

Even though most participants mention that financial benefit is the most rated motivation. Participants were also asked to rate which factors were more important for deciding to join a study, firstly majority 23(40.4%) agreed there decision was based on the type of drug to be tested. Participants perceived that the type of drug that is being tested (familiarity) of the drug is the major decision factor to enroll in the trial. Particularly for this trial of herbal remedy participants mentioned they use them at home without any scientific approval so they thought the amount of risk would be less. Similarly a study done on volunteers in a phase I Pfizer trial in the US, Belgium and Singapore showed that preferences were for familiar and low risk studies and

procedures (43). Furthermore study on three different country's showed that other than the money participants has considered the risk for decision making (9). And also a study in Tanzania showed that one of the barriers for the participation on the herbal remedy trial was the possible occurrence of risk which may be irreversible (42). The second factor that most agreed with a mean of 3.72 that helped them for the decision making was to help future patients as it is one important motivation and it is also a decision factor cause participants stressed that the production of certain trials similar to this one are beneficial for the growth and promotion of developing herbal remedies in to modern medicine. This is similar to study (4,9,24,42). In an effort to explain the reason to help other maybe cultural and spirituality of participants. The other factor is the presence of medical care at the trial center. In the study we found that participants decided to join the study due to the presence of medical care during the occurrence of adverse event. This finding is in agreement with that of previous study in United States were participants decision was based on the competency of the CRF staff (9). Similarly another study also stated that trust in the general research oversight system and specific phase I clinics can protect them from harm (30).

The other important finding of the study was that participants never wanted anyone to know their participation in the phase I trial because there was societal discouragement, and participants mentioned the low level of awareness society has for phase I trials. Only 42.1% of the participants told their families, and out of them, only 14.0% had a positive response. The majority (28.1%) of them were afraid of the risk that may happen during the study. This finding is in agreement with the study done in Korea and China were volunteers thought that public perceptions of clinical trials were negative and that the public was uninformed about clinical trials (4,39). Time inconvenience was not that much of a problem for the majority of participants in this study since they were from close-by areas, but for those who came from distant areas, the amount of compensation and the time incontinence were major challenges. This is similar to the study in the US where time inconvenience was the major barrier for the participants in the trial (9), and also in the herbal remedy trial in Tanzania (42) where participants mentioned that one factor in deciding to join a trial is a flexible schedule.

6.1. Strengths and limitations of the study

This is the first kind of study conducted on the motivation of healthy volunteers on herbal medicine in phase I clinical trial conducted in Ethiopia. Since the number of phase I trials being conducted in Ethiopia are increasing, it is important to understand their motives and work on the ethical protection of healthy volunteers. The other strength is the use of mixed-method research to get a better picture of the question at hand.

The limitation of the study is that since only those who had been involved in the study were involved, the opinions of the rest of the healthy volunteer may be different. The other is that since it was an interviewer-assigned survey, there may be different biases, such as social desirability, self-reporting, non-response biases, and recall bias.

7. CONCLUSIONS

The healthy volunteers in this study are mostly motivated by the financial benefit they receive, even though most of the participants had full-time jobs with low monthly income. The contribution to the development of new trial drugs is also another motivational factor Even though the money was a motivating factor; most participants indicated that the type of drug was the most important consideration because it would determine the risk. Because the participants used the herbs at home, they also believed that the trial's risk was very low, and in the event that an adverse event occurred, they mostly relied on the medical care offered. The other is the belief of altruism: the production of herbal remedies benefit can be more effective and accessible for society than drugs that are produced abroad, which are the main factors in deciding to join a trial. Furthermore, participants were affected by societal awareness about clinical trials, causing them to feel stressed after joining the trial.

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8. RECOMMENDATION

- Since the majority of the participants are from low socio-economic status the amount of money may motivate them to participate but the trial site should be careful while recruiting healthy volunteers the risk of the study should be clearly stated for the participants and different evaluating materials should be prepared to test how much the participant has understood the risk in the trial.
- Addressing the negative perception of clinical trials among the society is crucial to protect participants from potential discrimination. This can be achieved through various strategies, such as conducting educational training programs, organizing forums to showcase the accomplishments of clinical trials, and enhancing post-trial access for the community. These efforts aim to foster understanding, appreciation, and acceptance of the valuable contributions made through clinical research.
- To enhance the convenience of participant's time for those traveling from distant areas, it is important to establish a flexible and accommodating time schedule that allows for the involvement of a diverse and representative participant pool. The procedures involved in the trial should be clearly explained and designed to be convenient for the participants. Additionally, participants should be provided with clear and comprehensive information regarding their health status following the conclusion of the trial. This ensures that participants have a positive experience and are well-informed about the outcomes of their involvement in the study.
- It is recommended that further study has to be done to explore the motive of healthy volunteers on different type of phase I trials and also involving views of the IRB and clinical trial site staff.

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10. ANNEX

10.1. Annex 1. Study tool

10.1.1 Interview Guide

The interview process will be facilitated by using the following interview guide with interviewees. It includes a series of questions, an information page, a consent form, and the interview objective.

Interview objective

- To investigate the experience of healthy volunteers on phases I clinical trial in Addis Ababa, Ethiopia in 2024.

Participant selection

- Participants will be selected from healthy volunteers participating in the phase I trial, it could be either bioequivalence or other drug tests taking place at the clinical trial

10.2. Annex 2. Participant Information sheet for qualitative

Title of the study: Exploring Healthy volunteers in phase I clinical trials: experience, perception and ethical concerns conducted in Addis Ababa Ethiopia.

I would like to thank you for taking the time to meet today, your contribution is greatly valued. My name is **Melat Gebremedhin**, master's student in MPH in health research ethics degree at Addis Ababa University. Currently, I am collecting data for a research project intended to identify the motive, experience, and perspective of healthy volunteer's on phase I clinical trials conducted in Addis Ababa Ethiopia**. Aim**: To understand the different ethical issues on phase I clinical trial

Participant selection

You are invited to participate in this study because of your experience in participating on phase I clinical trial at the study site were the study takes place.

Study Procedure: A face to face in-depth interview will be contacted. It will take place at the participant convenient location. The interview will likely take around 25 to 30 minutes to complete. The interview will be audio-recorded and a note book will be used to record important information's.

Confidentiality: All information will remain confidential. All the responses you provide are anonymous. Information on the report will be de-identified. You won't be obliged to response to any question you don't want to respond. You have the right to withdraw from the study without any giving any reason.

Benefit: The study may not have any direct or immediate benefit to you, but your participation is very important for the outcome of the study and gives direction for future study and improvement in phase I clinical trial service. And also for the cost of transportation and time spent for the interview will be compensated with 200 ETB.

Risk: there are no foreseeable risks that you will encounter by participating in this study, except for the time spent in participating. The interview guide may contain sensitive topic. You may decline to answer any question that you find uncomfortable and you do not have to give any reason for not responding to the question.

Voluntary participation

Your participation in this research is voluntary. It is your choice whether or not to participate on this study. If you decide to participate you will be asked to sign consent form. You can withdraw from the study at any time even after you have signed the consent form. There will not be any consequence or loss of benefit if you decide to withdraw from the study.

Contact information

Investigators: Melat Gebremedhin Tel: 0936960547 Mail: melatgebremedhin5@gmail.com

Dr Adamu addissie Tel: +251911404954 Mail: adamuaddissie@gmail.com

AAERC Tel: +251118342742 Mail: ahri.alerterc@ahri.gov.et

10.3 Annex 3. Consent form

I was provided on the information that the study is being conducted to know the perspective of phase I participants, and the study has been explained to me in the language I understand and that all information I provided will be kept confidential, I understand that participation is volunteer and that I can withdraw at any time without giving any reason, it is explained that the researcher may use some of the exact word of the participant but I understand that it will be anonymous,

I understand all the information given above and agreed to participate in this study by interest.

Signature of participant's: _____

Date: ___/___/_____

Consent provider name _____ Date _____

10.4. Annex 4. Participants Information sheet for quantitative

Title of the study: Exploring Healthy volunteers in phase I clinical trials: experience, perception and ethical concerns conducted in Addis Ababa Ethiopia.

I would like to thank you for taking the time to meet today, your contribution is greatly valued. My name is **Melat Gebremedhin**, master's student in MPH in health research ethics degree at Addis Ababa University. Currently, I am collecting data for a research project intended to identify the motive, experience, and perspective of healthy volunteer's on phase I clinical trials conducted in Addis Ababa Ethiopia**.**

Aim: To understand the different ethical issues on phase I clinical trial

Participant selection

You are invited to participate in this study because of your experience in participating on phase I clinical trial at the study site were the study takes place.

Study Procedure: A face to face structured interview will be contacted. It will take place at the participant convenient location. The interview will likely take around 15 minutes to complete. The interview will be recorded on the Questionnaire.

Confidentiality: All information will remain confidential. All the responses you provide are anonymous. Information on the report will be de-identified. You won't be obliged to response to any question you don't want to respond.

Benefit: The study may not have any direct or immediate benefit to you, but your participation is very important for the outcome of the study and gives direction for future study and improvement in phase I clinical trial service. And also for the cost of transportation and time spent for the interview will be compensated with 200 ETB.

Risk: there are no foreseeable risks that you will encounter by participating in this study, except for the time spent in participating. The interview questions may contain sensitive topic. You may decline to answer any question that you find uncomfortable and you do not have to give any reason for not responding to the question. Refusal to participate will not affect your participation in the current and future studies.

Voluntary participation

Your participation in this research is voluntary. It is your choice whether or not to participate on this study. If you decide to participate you will be asked to sign consent form. You can withdraw from the study at any time even after you have signed the consent form. There will not be any consequence or loss of benefit if you decide to withdraw from the study.

Contact information

Investigators: Melat Gebremedhin 0936960547 . Mail melatgebremedhin5@gmail.com

You can also contact the AAERC Tel: +251118342742 Mail : ahri.alerterc@ahri.gov.et

You can also contact Tel: +251911404954 Mail: adamuaddissie@gmail.com

Annex 5. Consent form

I was provided on the information that the study is being conducted to know the perspective of phase I participants, and the study has been explained to me in the language I understand and that all information I provided will be kept confidential, I understand that participation is volunteer and that I can withdraw at any time without giving any reason.

I understand all the information given above and agreed to participate in this study by interest.

Signature of participant's: _____

Date: ___/___/_____

Consent provider name _____ Date _____

10.6. Annex 6: Code book: Research on exploring healthy volunteers perception and motivation in phase I clinical trial

Code book: Research on exploring healthy volunteers perception and motivation in phase I clinical trial				
Theme	**Categories**	**Codes**	**Description**	**What it covers**
Participant impression on phase I trial	Awareness, Source of advertisement	Prior exposure, source of information, ,knowledge	How participant understand what clinical trial is and how they get the information	Includes volunteers awareness and source of information about clinical trial
Motivation of healthy volunteers	Financial, Gain knowledge, Altruism, health cheek up	Family support, Financial benefit, Health cheek up, societal benefit, change the community, future patients, curiosity	Explain about what motivates volunteers to participate in the trial	Includes all different motives of participants
Consideration during decision to take part in the study	Competency of the research team, Type of drug, Health status, Scientifically proven,	Dosage, Eligibility, familiarity, Local drug production, Self-reliance, Insurance of study, national benefit, dependency, decreased initial interest, production process	Explains about what options or consideration has the volunteer taken in to consideration before deciding to take part in the study.	Includes all possible list of consideration taken in to account to join a trial
Perceived disadvantage	Negative consequences, Time inconvenience, Possible Side effect of the drug	Burning sensation, little itching, discomfort, scarify, Disturbed sleep, Additional substance, worry, side effect, less time, contagious(contracting the disease),	Explain about the risk participants encounter while participating in the study	Includes the what the participants perceive as the possible disadvantage of participating on a herbal trial
Barriers for healthy volunteers	Confidentiality, insufficient compensation, Root of application of the drug, Comunication of final result	Accessible, Expectation, Transport cost, concern, secret, site of application, unappreciated, Adequacy of the incentive, emotional support,	Explains what barriers volunteers face in the study	Includes all possible barriers participant face during the study
Perceived community response	Social pressure, , societal discrimination,	misunderstanding, greedy, Experimental animal, Judgment, Awareness, consultation, Angry, peer pressure,	What the society thinks of them participating in a trial	Includes different aspects of stress brought up on participants by the society

10.7 Annex 7. Qualitative question guide

S/N	Questions	Probing
1	Before participating in this trial, how did you understand what a clinical trial is and what it involves?	
2	What motivated you participate in clinical trials?	
3	Before participating, did you ask someone else's opinion about your participation? How did they react regarding your participation? What reasons did they give?	To participate or not to?
4	How do you consider the financial reward in this clinical trial?	In evaluating the importance of the financial incentive, what factors do you take into account?
5	In your evaluation of the consent information presented before participating, how do you perceive the adequacy and clarity of the provided information?	
6	What factors are you considering importantly when you make a decision to participate in clinical trial?	
7	How do you consider the inconvenience/ discomfort in relation to the information provided before trial?	
8	How would you describe your level of satisfaction or dissatisfaction with the procedures during the trial phase?	
9	What were your emotions regarding the potential occurrence of a significant complication during this trial?	Did any side effect on you during the trial Or did any other participants tell you if they have encountered any side effect

	Questionnaire ID		
	Date of interview		
Part 1-Sociodemographic Information			
S/N	**Questions**	**Options/ answers**	**Skipping**
101	Age	----------	
102	Sex	1. Male 2. Female	
103	What is your current Marital status	1. Single 2. Married 3. Divorced 4. Widowed	
104	What is your current employment status	1. Student 2. Full time 3. Part time 4. Unemployed	
105	What is the highest educational status you have attained	1.Can read and write 2.No education 3.Primary 4.Secondary 5.Tertiary and above	
106	What is your average monthly income	----------	
107	What is your current occupational status	1. Student 2. Full time 3. Part time 4. unemployed	
108	What is your current type of residence	1.With family as a family dependent 2. As a head of the family 3. Alone	
109	Housing condition	1. Family-owned 2. My own house 3. Rent house 4. Dormitory (if university student)	
Part 2. Experience and perception in clinical trials			
202	How many times did you participate in clinical trial including this one?	1.One 2.Two 3. More than three	
203	What motivated you to participate in clinical trial?	Grade 1-5 points (1 very low, 2 low, 3 average, 4 high, 5very highly)	
	Because I can contribute to making a		

	progress of medicine by discovering new knowledge		
	Because I can get a chance to have a free health check-up		
	Because I have curiosity about clinical trials		
	Because I can receive financial reward for participation		
	Advice from family and friends		
204	Would you participate in the trial even though you didn't receive any financial reward	1. Yes I would 2. I am not sure 3. No I would not	

205	The way of acquiring information about the trial	1. Though the poster and notification 2. From staff of the hospital or clinical trial 3. From former participants	Can select multiple items
206	Before participating did you ask someone else opinion about your participation	1. Yes, I asked opinion 2. No, I Didn't ask opinion	Q #207 208, 209, 210 Q #211
207	Whom did you ask opinion about your participation	1. family member/partner 2. friend 3. health professional	Can select multiple items
208	How did they react regarding your participation	1. Almost all said yes 2. some said yes but some no 3. Almost all said no 4. All said no	
209	If they recommended you not to participate what was their reason?	1. risk of clinical trial 2. perception of genie pig 3. Miss work or school	
210	If they recommended you not to participate did they have any experience participating in a clinical trial before?	1. Yes 2. No	
211	How do you consider the final reward in the clinical trial you participated	1. satisfactory/good 2. Reasonable 3. Unsatisfactory/bad	
212	What factors do you consider important in deciding to join the clinical trial	Grade 1-5 points (1 very low, 2 low, 3 average, 4	

		high, 5very highly important)	
	Risk in health from adverse events to investigational drugs		
	Length of participating period in clinical trial		
	Frequency and type of procedures and examination in clinical trial		
	Loss of income to be acquired unless you participate in clinical trial		
	Type of drug		
	The time it takes for the procedure		
	For helping future patients		
	The presence of medical care at the CRO		

214	Which particular	Grade 1-5 points (1 very low, 2 low, 3 average, 4 high,)	
	Herbal drug		
	Particular study/Procedure		
	Better Payment		
	Root of application		
217	Was your actual experience in this trial different from the information provided before your participation during consent	1. Yes 2. No	
219	How did you fill about the occurrence of serious complication during the trial	1. I never feel that possibility 2. Occasionally I feel that possibility 3. I feel that possibility for a significant period of time	
220	Would you participate on a healthy volunteer clinical trial again?	1. Yes, I would 2. I am not sure 3. No, I would not	
221	what do you think the amount of risk	1. none 2.low 3.medium 4.high 5.very high	
222	Do you think you're safe from harm?	1.yes 2. no	

10.3 Annex 8. Amharic version informed consent

ለጥናቱ ተሳታፊ የጥናቱ መረጃ እና የስምምነት ማረጋገጫ
እትም እና ቀን V1.0 ጥር 25, 2024

የጥናቱ ርዕስ፡ በአዲስ አበባ ኢትዮጵያ የሚካሄዱ በምዕራፍ አንድ ክሊኒካዊ ሙከራዎች የጤናማ በጎ ፈቃደኞችን ፡ ልምድ፣ ግንዛቤ እና የስነምግባር ጉዳዮች ማሰስ ።

ዛሬ ለመገናኘት ጊዜ ስለወሰዱ ላመሰግናችሁ እወዳለሁ፣ የእርስዎ አስተዋፅዖ በጣም የተከበረ ነው። ስሜ ሜላት ገብረመድህን እባላለሁ በአዲስ አበባ ዩኒቨርሲቲ በጤና ጥናትና ምርምር ስነምግባር በ MPH የማስተርስ ተማሪ ነች። በአሁኑ ጊዜ በአዲስ አበባ ኢትዮጵያ ውስጥ በተደረገው የደረጃ አንድ ክሊኒካዊ ሙከራዎች ጤናማ በጎ ፈቃደኞች የስነምግባር ጉዳዮችን ለመለየት የታሰበ የምርምር ፕሮጀክት መረጃ እየሰበሰብኩ ነው።

ዓላማ፡- በክፍል አንድ ክሊኒካዊ ሙከራ ላይ ያሉትን የተለያዩ የሥነ ምግባር ጉዳዮች ለመረዳት

የተሳታፊ ምርጫ

በዚህ ጥናት ላይ እንድትሳተፉ ተጋብዘዋል ምክንያቱም ጥናቱ በተካሄደበት በጥናቱ ቦታ በክፍል አንድ ክሊኒካዊ ሙከራ ላይ የመሳተፍ ልምድ ስላሎት።

የጥናት ሂደት፡- በዕዳ ውስጥ ፊት ለፊት የሚደረግ ቃለ መጠይቅ ይገናኛል። በተሳታፊው ምቹ ቦታ ላይ ይከናወናል. ቃለ መጠይቁ ለማጠናቀቅ ከ25 እስከ 30 ደቂቃዎች አካባቢ ሊወስድ ይችላል። ቃለ-መጠይቁ በድምጽ የተቀዳ እና አስፈላጊ መረጃዎችን ለመቅዳት ማስታወሻ ደብተር ጥቅም ላይ ይውላል። የጥናት ጥያቄውን ለመመለስ የተዘጋጁ ጥያቄዎችን እንዲመልሱ ይጠየቃሉ እና መረጃ በመቅጃ እና በማስታወሻ ደብተር በመጠቀም ይሰበሰባል.

ምስጢራዊነት፡ ሁሉም መረጃዎች ሚስጥራዊ እንደሆኑ ይቆያሉ። ሁሉም የሰጡት ምላሾች ስም-አልባ ናቸው። በሪፖርቱ ላይ ያለው መረጃ አይታወቅም. ምላሽ መስጠት ለማትፈልጉት ለማንኛውም ጥያቄ ምላሽ የመስጠት ግዴታ አይኖርብዎትም። ያለ ምንም ምክንያት ከጥናቱ የመውጣት መብት አልዎት።

ጥቅሞች፡ ጥናቱ ለእርስዎ ምንም አይነት ቀጥተኛም ሆነ ፈጣን ጥቅም ላይኖረው ይችላል፣ነገር ግን የእርስዎ ተሳትፎ ለጥናቱ ውጤት በጣም አስፈላጊ ነው እና ለወደፊት ጥናት እና በክፍል አንድ ክሊኒካዊ የሙከራ አገልግሎት መሻሻል አቅጣጫ ይሰጣል። እንዲሁም ለትራንስፖርት ወጪ እና ለቃለ-መጠይቁ የሚፈጀው ጊዜ በ 200 ብር ይከፈላል.::

ስጋት፡ በዚህ ጥናት ውስጥ በመሳተፍ የሚያጋጥሙዎት ሊገመቱ የሚችሉ ስጋቶች የሉም፣ በመሳተፍ ጊዜ ካለፈው በስተቀር። የቃለ መጠይቁ ጥያቄዎች ሚስጥራዊነት ያለው ርዕስ ሊይዙ ይችላሉ። የማይመቹዎትን ማንኛውንም ጥያቄ ለመመለስ እምቢ ማለት ይችላሉ እና ለጥያቄው ምላሽ የማይሰጡበት ምንም ምክንያት መስጠት የለብዎትም። ለመሳተፍ ፈቃደኛ አለመሆን አሁን ባሉት እና ወደፊት በሚደረጉ ጥናቶች ውስጥ ያለዎትን ተሳትፎ አይጎዳውም::

በፈቃደኝነት ተሳትፎ

በዚህ ጥናት ውስጥ ያለዎት ተሳትፎ በፈቃደኝነት ነው። በዚህ ጥናት ላይ መሳተፍ ወይም አለመሳተፍ የእርስዎ ምርጫ ነው። ለመሳተፍ ከወሰኑ የስምምነት ቅጽ ላይ እንዲፈርሙ ይጠየቃሉ። የስምምነት ቅጹን ከፈረሙ በኋላም ቢሆን በማንኛውም ጊዜ ከጥናቱ መውጣት ይችላሉ። ከጥናቱ ለመውጣት ከወሰኑ ምንም አይነት ውጤት ወይም ጥቅማጥቅሞች አይኖሩም።

ጥያቄ ካሎተት ከታች ባሉት አድራሻ ይጠቀሙ

ተመራማሪ፡ ሜላት ገብረመድህን 0936960547 በኢሜል ፡ melatgebremedhin5@gmail.com

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እንዲሁም ዶር አዳሙ አዲሴ በስልክ ቁጥር +251911404954 በኢሜል: adamuaddissie@gmail.com

Annex 10. Amharic version consent

በጥናቱ ለመሳተፍ የስምምነት ማረጋጋጫ ቅጽ

ጥናቱ የሚካሄደው የምዕራፍ አንድ ተሳታፊዎችን ለማወቅ መሆኑን መረጃ ተሰቶኛል፣ ጥናቱም በምረዳው ቋንቋ ተብራርቶልኛል እና ያቀረብኩት መረጃ ሁሉ በሚስጥር እንደሚጠበቅ ተረድቻለሁ፣ ተሳትፎውም በፈቃደኝነት እና በማንኛውም ጊዜ ምንም ምክንያት ሳልገልጽ መውጣት እንደምችል ተገንዝቢያለሁ።

ከላይ የተገለጹትን መረጃዎች በሙሉ ተረድቻለሁ እናም በዚህ ጥናት ውስጥ በፍላጎት ለመሳተፍ ተስማምቻለሁ።

የተሳታፊዎች ፊርማ፡ _____

ቀን፡ ___/__/____

ስምምነቱን ያስፈለመዉ ሰው : _____ ቀን _____

ለጥናቱ ተሳታፊ የጥናቱ መረጃ እና የስምምነት ማረጋገጫ
እትም እና ቀን V1.0 ጥር 25, 2024

የጥናቱ ርዕስ፡ በአዲስ አበባ ኢትዮጵያ የሚካሄዱ በምዕራፍ አንድ ክሊኒካዊ ሙከራዎች የጤናማ በጎ ፈቃደኞችን ፡ ልምድ፣ ግንዛቤ እና የስነምግባር ጉዳዮች ማሰስ ።
ዛሬ ለመገናኘት ጊዜ ስለወሰዱ ላመሰግናችሁ እወዳለሁ፣ የእርስዎ አስተዋፅዖ በጣም የተከበረ ነው። ስሜ ሜላት ገብረመድህን እባላለሁ በአዲስ አበባ ዩኒቨርሲቲ በጤና ጥናትና ምርምር ስነምግባር በ MPH የማስተርስ ተማሪ ነች። በአሁኑ ጊዜ በአዲስ አበባ ኢትዮጵያ ውስጥ በተደረገው የደረጃ አንድ ክሊኒካዊ ሙከራዎች ጤናማ በጎ ፈቃደኞች የስነምግባር ጉዳዮችን ለመለየት የታሰበ የምርምር ፕሮጀክት መረጃ እየሰበሰብኩ ነው።

ዓላማ፡- በክፍል አንድ ክሊኒካዊ ሙከራ ላይ ያሉትን የተለያዩ የሥነ ምግባር ጉዳዮች ለመረዳት

የተሳታፊ ምርጫ

በዚህ ጥናት ላይ እንድትሳተፉ ተጋብዘዋል ምክንያቱም ጥናቱ በተካሄደበት በጥናቱ ቦታ በክፍል አንድ ክሊኒካዊ ሙከራ ላይ የመሳተፍ ልምድ ስላሎት።

የጥናት ሂደት፡- በዕዳ ውስጥ ፊት ለፊት የሚደረግ ቃለ መጠይቅ ይገናኛል። በተሳታፊው ምቹ ቦታ ላይ ይከናወናል. ቃለ መጠይቁ ለማጠናቀቅ ከ15 ደቂቃዎች አካባቢ ሊወስድ ይችላል። የጥናት ጥያቄውን ለመመለስ የተዘጋጁ ጥያቄዎችን እንዲመልሱ ይጠየቃሉ እና መረጃ ይሰበሰባል።

ምስጢራዊነት፡ ሁሉም መረጃዎች ሚስጥራዊ እንደሆኑ ይቆያሉ። ሁሉም የሰጡት ምላሾች ስም-አልባ ናቸው። በሪፖርቱ ላይ ያለው መረጃ አይታወቅም. ምላሽ መስጠት ለማትፈልጉት ለማንኛውም ጥያቄ ምላሽ የመስጠት ግዴታ አይኖርብዎትም። ያለ ምንም ምክንያት ከጥናቱ የመውጣት መብት አልዎት።

ጥቅሞች፡ ጥናቱ ለእርስዎ ምንም አይነት ቀጥተኛም ሆነ ፈጣን ጥቅም ላይኖረው ይችላል፣ነገር ግን የእርስዎ ተሳትፎ ለጥናቱ ውጤት በጣም አስፈላጊ ነው እና ለወደፊት ጥናት እና በክፍል አንድ ክሊኒካዊ የሙከራ አገልግሎት መሻሻል አቅጣጫ ይሰጣል። እንዲሁም ለትራንስፖርት ወጪ እና ለቃለ-መጠይቁ የሚፈጀው ጊዜ በ 200 ብር ይከፈላል.::

ስጋት፡ በዚህ ጥናት ውስጥ በመሳተፍ የሚያጋጥሙዎት ሊገመቱ የሚችሉ ስጋቶች የሉም፣ በመሳተፍ ጊዜ ካለፈው በስተቀር። የቃለ መጠይቁ ጥያቄዎች ሚስጥራዊነት ያለው ርዕስ ሊይዙ ይችላሉ። የማይመቹዎትን ማንኛውንም ጥያቄ ለመመለስ እምቢ ማለት ይችላሉ እና ለጥያቄው ምላሽ የማይሰጡበት ምንም ምክንያት መስጠት የለብዎትም። ለመሳተፍ ፈቃደኛ አለመሆን አሁን ባሉት እና ወደፊት በሚደረጉ ጥናቶች ውስጥ ያለዎትን ተሳትፎ አይጎዳውም::

በፈቃደኝነት ተሳትፎ

በዚህ ጥናት ውስጥ ያለዎት ተሳትፎ በፈቃደኝነት ነው። በዚህ ጥናት ላይ መሳተፍ ወይም አለመሳተፍ የእርስዎ ምርጫ ነው። ለመሳተፍ ከወሰኑ የስምምነት ቅጽ ላይ እንዲፈርሙ ይጠየቃሉ። የስምምነት ቅጹን ከፈረሙ በኋላም ቢሆን በማንኛውም ጊዜ ከጥናቱ መውጣት ይችላሉ። ከጥናቱ ለመውጣት ከወሰኑ ምንም አይነት ውጤት ወይም ጥቅማጥቅሞች አይኖሩም።

ጥያቄ ካሎተት ከታች ባሉት አድራሻ ይጠቀሙ

ተመራማሪ፡ ሜላት ገብረመድህን 0936960547 በኢሜል ፡ melatgebremedhin5@gmail.com

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ማግኘት ይችላሉ።

በጥናቱ ለመሳተፍ የስምምነት ማረጋጋጫ ቅጽ

ጥናቱ የሚካሄደው የምዕራፍ አንድ ተሳታፊዎችን አመለካከት ለማወቅ መሆኑን መረጃ ተሰቶኛል፣ ጥናቱ በምረዳው ቋንቋ ተብራርቶልኛል እና ያቀረብኩት መረጃ ሁሉ በሚስጥር እንደሚጠበቅ ተረድቻለሁ፣ በ በጎ ፈቃደኛ እና በማንኛውም ጊዜ ምንም ምክንያት ሳልገልጽ መውጣት እንደምችል ተመራማሪው የተወሰነውን የተሳታፊውን ትክክለኛ ቃል ሊጠቀሙ እንደሚችሉ ተብራርቷል ነገር ግን ማንነቱ እንደ ማይታወቅ እንደሚሆን ተረድቻለሁ።

ከላይ የተገለጹትን መረጃዎች በሙሉ ተረድቻለሁ እናም በዚህ ጥናት ውስጥ በፍላጎት ለመሳተፍ ተስማምቻለሁ።

የተሳታፊዎች ፊርማ፡ _____

ቀን፡ ___/__/____

ስምምነቱን ያስፈለመዉ ሰው : _____ ቀን _____

፲፩ Annex 11. Amharic version questionnaire

ክፍል 1 የተሳታፊ መረጃ

1 . በዚህ ሙከራ ውስጥ ከመሳተፍዎ በፊት ክሊኒካዊ ሙከራ ምን እንደሆነ እና ምን እንደሚያካትት

እንዴት ተረዱ?

2. በክሊኒካዊ ሙከራዎች ውስጥ የሚሳተፉበት ምክንያት ምንድን ነው?

3. ከመሳተፍዎ በፊት ስለ እርስዎ ተሳትፎ የሌላ ሰው አስተያየት ጠይቀዋል? ስለ እርስዎ ተሳትፎ ምን ምላሽ ሰጡ? መሳተፍ እንደሌለብህ ቢመከሩ; ምን ምክንያቶች ሰጡ? መሳተፍ እንደሌለብዎት ሲጠቁሙ፣ ከዚህ በፊት በክሊኒካዊ ሙከራዎች ውስጥ የመሳተፍ ልምድ ነበራቸው?

4. የገንዘብ (የፋይናንስ) ማበረታቻውን አስፈላጊነት ሲገመግሙ የትኞቹን ነገሮች ግምት ውስጥ ያስገባሉ?

5. ከመሳተፍዎ በፊት የቀረበውን የስምምነት መረጃ ሲገመግሙ፣ የቀረበውን መረጃ በቂነት እና ግልጽነት

እንዴት ያዩታል?

6. በክሊኒካዊ ሙከራ ውስጥ ለመሳተፍ ውሳኔ ሲያደርጉ የትኞቹን ነገሮች በቁም ነገር እያጤኑ ነው?

7. በዚህ ሙከራ ውስጥ ያጋጠመዎት ልምድ ከመሳተፍዎ በፊት ከቀረቡት መረጃዎች የተለየ ነበር?

8. በተሳትፎዎ ወቅት የነበሮትን ቆጠይታ የተደሰቱበት ወይም ያልተመችዎት ነገር ነበር ?

9. በዚህ ሙከራ ወቅት ሊፈጠሩ ለሚችሉ ችግሮች ያሎት ስሜት ምን ነበር?

ተ.ቁ	ጥያቄ	ምላሽ	አስተያየት
101	ዕድሜ		
102	ጸታ	1. . ወንድ 2. ሴት	
103	አሁን ያለህበት/ሽ የጋብቻ ሁኔታ ምንድን ነው	1. ያላገባ 2. ያገባ 3. የተፋታ 4. ባል የሞተባት/በት	
104	አሁን ያለህበት የስራ ሁኔታ ምን ይመስላል	1. ተማሪ 2. የሙሉ ጊዜ 3. የትርፍ ጊዜ 4. ሥራ አጥ	
105	ያገኙት ከፍተኛ የትምህርት ደረጃ ምንድ ነው	1. ማንበብና መጻፍ የሚችል 2. ትምህርት የለም 3.ዋና 4.ሁለተኛ ደረጃ 5.መሰናዶ እና ከዚያ በላይ	
106	አማካይ ወርሃዊ ገቢዎ ስንት ነው	----------	
107	አሁን ያለህበት የሙያ ደረጃ ምን ይመስላል	1. ተማሪ 2. የሙሉ ጊዜ 3. የትርፍ ጊዜ 4. ሥራ አጥ	
108	አሁን ያለዎት የመኖሪያ አይነት	1.ከቤተሰብ ጋር 2.ለብቻ	

201	ይህንን ጨምሮ በክሊኒካዊ ሙከራ ውስጥ ስንት ጊዜ ተሳትፈዋል?	1. አንድ 2.ሁለት 3. ሶስት 4.ከሦስት በላይ	
202	203 በክሊኒካዊ ሙከራ ውስጥ የሚሳተፉበት ምክንያት ምንድን ነው?	ነጥብ 1-5 ነጥብ	
	1. ምክንያቱም አዳዲስ እውቀቶችን በማግኘት ለህክምና እድገት አስተዋጽኦ ማድረግ እችላለሁ		
	2. ምክንያቱም ነፃ የጤና ምርመራ ለማድረግ እድል ማግኘት እችላለሁ		
	3. ምክንያቱም ስለ ክሊኒካዊ ሙከራዎች የማወቅ ጉጉት አለኝ		
	4. ምክንያቱም ለተሳትፎ የገንዘብ ሽልማት ማግኘት እችላለሁ		
	5. ሌሎች		
203	ምንም የገንዘብ ሽልማት ባይቀበሉም በሙከራው ላይ ይሳተፋሉ	1. አዎ አደርጋለሁ 2. እርግጠኛ አይደለሁም 3. አይ አልፈልግም። 4. ሌላ	
204	ስለ ችሎቱ መረጃ የማግኘት	መንገድ 1. ፖስተር እና ማሳወቂያ ቢሆንም 2. ከሆስፒታሉ ሰራተኞች ወይም ክሊኒካዊ ሙከራ 3. ከቀድሞ ተሳታፊዎች 4. ሌላ	ከ አንድ በላይ መምረጥ ይችላሉ
205	ከመሳተፍዎ በፊት ስለ እርስዎ ተሳትፎ የሌላ ሰው አስተያየት ጠይቀዋል	1. አዎ፣ አስተያየት ጠየቅኩ። 2. አይ, አስተያየት አልጠየቅኩም	
206	ስለ እርስዎ ተሳትፎ አስተያየት የጠየቁት	1. የቤተሰብ አባል/ባልደረባ 2. ጓደኛ 3. የጤና ባለሙያ 4. ያልተገለጸ/የድር ፍለጋ 5. ሌላ_____ ብዙ እቃዎችን መምረጥ ይችላል።	
207	የእርስዎን ተሳትፎ በተመለከተ ምን ምላሽ ሰጡ	1. ሁሉም ማለት ይቻላል አዎ አሉ። 2. አንዳንዶች አዎ ግን አንዳንዶቹ አይደለም አሉ። 3. ሁሉም ማለት ይቻላል አይሆንም አሉ።	

		4. ሁሉም አይደለም አሉ። 5. ሌላ_____	
208	እንዳትሳተፍ ቢመክሩህ ምክንያታቸው ምን ነበር?	1. የክሊኒካዊ ሙከራ አደጋ 2. የጂኒ አሳማ ግንዛቤ 3. ናፍቆት ስራ ወይም ትምህርት ቤት 4. ከቤት ርቆ 5. ሌላ	
209	እንዳትሳተፍ ቢመክሩህ ከዚህ በፊት በክሊኒካዊ ሙከራ ውስጥ የመሳተፍ ልምድ ነበራቸው?	1. አዎ ሁሉም የቀድሞ ተሳታፊዎች ናቸው። 2. አንዳንዶቹ የቀድሞ ተሳታፊዎች ናቸው 3. አይ, የቀድሞ ተሳታፊዎች አይደሉም 4. እርግጠኛ አይደለሁም 5. ሌላ_____	
210	በዚህ ክሊኒካዊ ሙከራ የመጨረሻውን ሽልማት እንዴት ይመለከቱታል	1. አጥጋቢ/ጥሩ 2. ምክንያታዊ 3. አጥጋቢ ያልሆነ / መጥፎ 4. ሌሎች_____	
211	የገንዘብ ሽልማትን ለመገምገም የትኞቹን አስፈላጊ ነገሮች ግምት ውስጥ ያስገባሉ።	ነጥብ 1-5 ነጥብ	
	ከአሉታዊ ክስተቶች እስከ የምርመራ መድሃኒቶች በጤና ላይ ስጋት		
	በክሊኒካዊ ሙከራ ውስጥ የመሳተፍ ጊዜ ርዝመት		
	በክሊኒካዊ ሙከራ ውስጥ ድግግሞሽ እና የአሠራር ዓይነቶች እና ምርመራ		
	በክሊኒካዊ ሙከራ ውስጥ ካልተሳተፉ በስተቀር የገቢ ማጣት		
	ሌላ		
212	ከመሳተፍዎ በፊት ለፈቃድዎ ያለውን መረጃ እንዴት ግምት ውስጥ ያስገባሉ	1. ከበቂ በላይ 2. በቂ 3. በቂ አይደለም 4. ሌላ__	
213	በክሊኒካዊ ሙከራው ውስጥ ለመሳተፍ ውሳኔ ሲያደርጉ ምን አስፈላጊ እንደሆኑ ያስባሉ	ነጥብ 1-5 ነጥብ	

	ከ የምርመራ መድሃኒት እና አሉታዊ ክስተቶች ባህሪያት		
	የጉብኝቶች ድግግሞሽ እና አጠቃላይ የክሊኒካዊ ሙከራ ጊዜ		
	በክሊኒካዊ ሙከራ ውስጥ ድግግሞሽ እና የአሠራር ሂደቶች እና ምርመራዎች ዓይነት		
	የመቀበል ጊዜ እና የገንዘብ ሽልማት መጠን		
	ሌሎች		
214	በዚህ ሙከራ ያጋጠማችሁት ከመሳተፋችሁ በፊት ከቀረበው መረጃ የተለየ ነበር	1. አዎ፣ የተለየ ነበር 2. አይ፣ የተለየ አልነበረም	
215	እባክዎን ከመሳተፍዎ በፊት እና በኋላ ያለውን ልዩነት ይግለጹ		
216	ከፍርድ ሂደቱ በፊት ከተሰጠው መረጃ ጋር በተያያዘ የተፈጠረውን ችግር እንዴት አገኛችሁት	1. ከተነገረው ያነሰ 2. ከተነገረው ጋር ተመሳሳይ 3. ከመረጃ በላይ 4. ሌላ____	
217	በዚህ ሙከራ በተሳትፎ ጊዜ ምን ያህል ረክተዋል	ነጥብ 1-5 ነጥብ	
	ምግብ ለእረፍት እና ለመመቻቸት መገልገያዎች		
	ለአደጋ ተሳታፊዎች ጥበቃ		
	የመርማሪዎች አመለካከት እና ብቃት		
	ለምርምር መገልገያዎች እና መሳሪያዎች ከመርማሪ ጋር ግንኙነት		
	ሌሎች		
218	በዚህ ሙከራዎ በተሳትፎበት ወቅት ምን ያህል እርካታ አልተሰማዎትም።	ነጥብ 1-5 ነጥብ	
	የመድሃኒት አስተዳደር		
	የደም ናሙና የአካል እና የላብራቶሪ ምርመራ		
	ምግብ ለእረፍት እና ለመመቻቸት መገልገያዎች		
	ከመርማሪዎች ጋር ግንኙነት		
	ሌሎች		

219	በሙከራው ወቅት ከባድ ችግር መከሰቱን እንዴት ሞላህ	1. ይህ ሊሆን እንደሚችል ፈጽሞ አይሰማኝም 2. አልፎ አልፎ ያንን እድል ይሰማኛል 3. ይህ እድል ለተወሰነ ጊዜ ያህል ይሰማኛል። 4. ሌላ____	
220	ጤናማ በሆነ የበጎ ፈቃደኝነት ክሊኒካዊ ሙከራ እንደገና መሳተፍ ይፈልጋሉ?	1. አዎ፣ አደርገዋለሁ 2. እርግጠኛ አይደለሁም 3. አይ, አላደርግም 4. ሌሎች	
221	ዘመዶችዎ ወይም ጓደኞችዎ በክፍል አንድ ሙከራ ላይ እንዲሳተፉ ይመክራሉ?	1. አዎ, አደርጋለሁ 2. እርግጠኛ አይደለሁም 3. አይ, አላደርግም 4. ሌሎች ___	