Version date: 10 July 2020

Development, acceptability, and feasibility of the Community-based mHealth Motivational Interviewing Tool (COMMIT) in Achham, Nepal

Nyaya Health Nepal/Possible + University of California, San Francisco

ClinicalTrials.gov NCT identifier: NCT04462679

INFORMED CONSENT - Patients

Investigators:

Bibhav Acharya, MD
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Community Health Director
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Investigator's Statement

You are invited to participate in a study conducted by the Ministry of Health, Nyaya Health Nepal-Possible, and the University of California, San Francisco. We hope to learn more about how to improve treatment adherence for patients with HIV by developing a mobile health application called COMMIT. You were selected as a possible participant in this study because you are receiving care as a patient with HIV. You also are eligible as you live in the Nyaya Health Nepal catchment area population in Achham District.

The purpose of this consent script is to give you the information you need to help you decide whether or not to be in the study. When all your questions have been answered, you can decide if you want to be in the study or not. This process is called "informed consent."

Procedures

If you agree, your participation will involve the following:

- Household healthcare visits: you will receive routine and follow-up clinical care from CHWs serving your community as determined by your medical record and healthcare needs; each visit with a provider will vary in length depending on your healthcare needs.
- Health outcome analysis: we will look at your medical records and analyze data on your health outcomes: (including: health outcomes, geographic location, caste/ethnicity, and medical history); no direct involvement beyond receiving routine clinical care. *More details on data to be analyzed can be provided; see protocol 14.4 Research Aims/17. Data Analysis plan.
- Focus group discussion: you may be invited to attend a focus group discussion with other participants from your community during pre-pilot testing (1 time). The discussion will take ~60 minutes. Your answers will be recorded and the interviewer(s) will take field notes. *Research staff may contact you to clarify your responses.
- Key-informant interview: you may be invited to attend an interview, one-on-one with a research staff member to assess acceptability (2 time) and feasibility (2 time). We will attempt to combine these interviews and the interview may last between 30-60 minutes. Your answers will be recorded and the interviewer(s) will take field notes. *Research staff may contact you to clarify your responses.

Risks and Benefits of the Study

You may not directly benefit from taking part in this study. However, we hope the program will provide you with improved clinical care. We also hope the results of the study will inform improvements to how CHWs deliver care for patients with HIV in Achham and throughout Nepal.

We will be developing a new mHealth application called COMMIT that will instruct CHWs with prompts to improve care for HIV patients and will audio record consented interactions with you and the CHW. The biggest risk for participation includes breach of privacy and disclosure of any personal information. This risk is mitigated in part by the application being layered onto an existing tool used by CHWs to deliver

care at the study site – CommCare. Developers and research staff members will ensure data quality assurance, privacy, and security standards are maintained at the highest levels.

Other Information
Any information that is obtained in connection with this study and that can be identified with you will remain confidential. When we share information from this study, it will not be connected with your name or family. Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the National Institutes of Health
- Representatives of the University of California

We may also wish to publish quotes arising from your focus group discussions and/or interview. These quotes will not contain any identifiable information about you or your child (including: name, age, sex, caste/ethnicity, subject/medical record identifiers, contact information, geographical address, and detailed information about your medical history). We may wish to use these quotes in one or more of the following publications:

- Journal article; open-access publication shared with research community
- Lay-press/newspaper article; either national or international news source
- Conference/symposium; poster, individual/group panel presentation
- Research student thesis/dissertation

Your decision to participate in this study and your responses during focus group discussions/interviews will not affect your care at (Bayalpata Hospital/CHWs in your community) now or in the future. If you decide to participate in the study, you can change your mind and withdraw your consent at any time during or after any of the procedures.

This research has been approved by the following bodies: the Nepal Health Research Council and the University of California, San Francisco IRB. If you have any questions, please ask us. If you have any additional questions later, contact the Director of Implementation Research at Bayalpata Hospital or inform your CHW, who will be happy to answer them.

You are making a decision whether or not to participate. Your verbal confirmation indicates that you have decided to participate, having been read and explained the information provided above.

[Please ask for participant to explain the study, procedures, risks/benefits to confirm their understanding. Encourage questions and provide any additional explanations.]

Date: _____

Verbal Consent (circle one): YES NO

[Indicate in CommCare [form field X/Y] their consent to participate in research study.]

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Nyaya Health Nepal/Possible + University of California, San Francisco

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INFORMED CONSENT - CHWs

Investigators:
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Aradhana Thapa
Community Health Director
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Investigator's Statement
You are invited to participate in a study conducted by the Ministry of Health, Nyaya Health Nepal-Possible, and the University of California, San Francisco. We hope to learn more about how to improve treatment adherence for patients with HIV by developing a mobile health application called COMMIT. You were selected as a possible participant in this study because you are a CHW employed by Nyaya Health Nepal, serving in Achham, and have been selected to receive motivational interviewing training.

The purpose of this consent script is to give you the information you need to help you decide whether or not to be in the study. When all your questions have been answered, you can decide if you want to be in the study or not. This process is called "informed consent."

Procedures
If you agree, your participation will involve the following:
- Formative research/prototype development of application: you will be invited to participate in an iterative design process to make the application. Your involvement will include participating in workshops where your feedback, through structured questions and unstructured discussions, will help create the application.
- Focus group discussion: you may be invited to attend a focus group discussion with other participants from your community during formative research (1 time), pre-pilot testing (1 time), and during acceptability testing (2 times) and feasibility testing (2 times). We will attempt to combine the acceptability and feasibility discussions. Each discussion will take ~60 minutes. Your answers will be recorded and the interviewer(s) will take field notes. *Research staff may contact you to clarify your responses.

Risks and Benefits of the Study
You may not directly benefit from taking part in this study. However, we hope the program will provide you with additional training to help you serve your patients and a mHealth application that will support your efforts. We also hope the results of the study will inform improvements to how our CHWs deliver care for patients with HIV in Achham and throughout Nepal.

We will be developing a new mHealth application called COMMIT that will instruct CHWs with prompts to improve care and will audio record consented interactions with you and the patient. The biggest risk for participation includes breach of privacy and disclosure of any personal information. Your interactions with patients will be recorded and then analyzed by our research team members. This risk is mitigated in part by the application being layered onto an existing tool used to deliver care at the study site – CommCare. Developers and research staff members will ensure data quality assurance, privacy, and security standards are maintained at the highest levels.

Other Information

Any information that is obtained in connection with this study and that can be identified with you will remain confidential. When we share information from this study, it will not be connected with your name or family. Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the National Institutes of Health
- Representatives of the University of California

We may also wish to publish quotes arising from your focus group discussions and/or interview. These quotes will not contain any identifiable information about you (including: name, age, sex, caste/ethnicity, subject/medical record identifiers, contact information, geographical address, and detailed information about your medical history). We may wish to use these quotes in one or more of the following publications:

- Journal article; open-access publication shared with research community
- Lay-press/newspaper article; either national or international news source
- Conference/symposium; poster, individual/group panel presentation
- Research student thesis/dissertation

Your decision to participate in this study and your responses during focus group discussions/interviews will not affect your employment or institutional affiliation (with the Ministry of Health and/or Nyaya Health Nepal-Possible) now or in the future. If you decide to participate in the study, you can change your mind and withdraw your consent at any time during or after any of the procedures.

This research has been approved by the following bodies: the Nepal Health Research Council and the University of California, San Francisco IRB. If you have any questions, please ask us. If you have any additional questions later, contact the Director of Implementation Research at Bayalpata Hospital who will be happy to answer them.

You are making a decision whether or not to participate. Your verbal confirmation indicates that you have decided to participate, having been read and explained the information provided above.

[Please ask for participant to explain the study, procedures, risks/benefits to confirm their understanding. Encourage questions and provide any additional explanations.]

Date: _____

Verbal Consent (circle one): YES NO

[If YES -> Proceed for inclusion in Focus Group Discussion/Key-Informant Interview.
If NO -> Remove from Focus Group Discussion/Key-Informant Interview participant list.]

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ClinicalTrials.gov NCT identifier: NCT04462679

INFORMED CONSENT – CHW Supervisors

Investigators:

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Aradhana Thapa
Community Health Director
CONTACT: +977 9851218352

Investigator's Statement

You are invited to participate in a study conducted by the Ministry of Health, Nyaya Health Nepal-Possible, and the University of California, San Francisco. We hope to learn more about how to improve treatment adherence for patients with HIV by developing a mobile health application called COMMIT. You were selected as a possible participant in this study because you supervise a CHW employed by Nyaya Health Nepal who has received training in motivational interviewing and who will use the COMMIT application.

The purpose of this consent script is to give you the information you need to help you decide whether or not to be in the study. When all your questions have been answered, you can decide if you want to be in the study or not. This process is called "informed consent."

Procedures

If you agree, your participation will involve the following:

- Formative research/prototype development of application: you will be invited to participate in an iterative design process to make the application. Your involvement will include participating in workshops where your feedback, through structured questions and unstructured discussions, will help create the application.
- Key Informant Interview: you may be invited to attend a semi-structured 1:1 interview with a research team member during formative research (1 time), pre-pilot testing (1 time), and during acceptability testing (2 times) and feasibility testing (2 times). We will attempt to combine the acceptability and feasibility interviews. Each interview will take ~30-60 minutes. Your answers will be recorded and the interviewer(s) will take field notes. *Research staff may contact you to clarify your responses.

Risks and Benefits of the Study

You may not directly benefit from taking part in this study. However, we hope the program will provide you (and the CHWs you work with) with additional training to help you serve your patients and a mHealth application that will support your efforts. We also hope the results of the study will inform improvements to how our CHWs deliver care for patients with HIV in Achham and throughout Nepal.

We will be developing a new mHealth application called COMMIT that will instruct CHWs with prompts to improve care and will audio record consented interactions with you and the CHW. The biggest risk for participation includes breach of privacy and disclosure of any personal information. Interactions between patients/CHWs will be recorded and then analyzed by our research team members. This risk is mitigated in part by the application being layered onto an existing tool used by CHWs to deliver care at the study site – CommCare. Developers and research staff members will ensure data quality assurance, privacy, and security standards are maintained at the highest levels.

Other Information

Any information that is obtained in connection with this study and that can be identified with you will remain confidential. When we share information from this study, it will not be connected with your name or family. Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the National Institutes of Health
- Representatives of the University of California

We may also wish to publish quotes arising from your interviews. These quotes will not contain any identifiable information about you (including: name, age, sex, caste/ethnicity, subject/medical record identifiers, contact information, geographical address, and detailed information about your medical history). We may wish to use these quotes in one or more of the following publications:

- Journal article; open-access publication shared with research community
- Lay-press/newspaper article; either national or international news source
- Conference/symposium; poster, individual/group panel presentation
- Research student thesis/dissertation

Your decision to participate in this study and your responses during focus group discussions/interviews will not affect your employment or institutional affiliation (with the Ministry of Health and/or Nyaya Health Nepal-Possible) now or in the future. If you decide to participate in the study, you can change your mind and withdraw your consent at any time during or after any of the procedures.

This research has been approved by the following bodies: the Nepal Health Research Council and the University of California, San Francisco IRB. If you have any questions, please ask us. If you have any additional questions later, contact the Director of Implementation Research at Bayalpata Hospital who will be happy to answer them.

You are making a decision whether or not to participate. Your verbal confirmation indicates that you have decided to participate, having been read and explained the information provided above.

[Please ask for participant to explain the study, procedures, risks/benefits to confirm their understanding. Encourage questions and provide any additional explanations.]

Date: _____

Verbal Consent (circle one): YES NO

[If YES -> Proceed for inclusion in Key-Informant Interview.
If NO -> Remove from Key-Informant Interview participant list.]

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ClinicalTrials.gov NCT identifier: NCT04462679

ASSENT FORM - Patients

Investigators:
Bibhav Acharya, MD
Mental Health Advisor
CONTACT: +977 986158502

Aradhana Thapa
Community Health Director
CONTACT: +977 9851218352

Investigator's Statement
You are invited to participate in a study conducted by the Ministry of Health, Nyaya Health Nepal-Possible, and the University of California, San Francisco. You have a disease called HIV-AIDS. We are using a new system to care for other children, adolescents, and adults who also have HIV-AIDS by providing your local Community Healthcare Worker (CHW) with more training and a mobile phone that helps them provide care. We want to see if you improve now that we are using this system. This is a science study. Maybe we will learn more about how to care for other sick children, adolescents, and adults with HIV-AIDS.

Procedures
If it's okay with you, we would like to:
- Provide care for you through your local CHW and at Bayalpata Hospital;
- Look at your medical record; and
- Depending on how the study proceeds, invite you to participate in either a group discussion (lasting ~1hr) and/or ask you some questions about your experience with the CHW (2 times, lasting ~30min-1hr).

We want to see how the doctors/CHW have treated you and if you are improving. We will make every effort to ensure these things happen at convenient times for you. We may also use quotes from your discussion/interview in a future publication, but we will not use your name or any information about you.

Other Information
We won't tell anyone you took part in this study. Your name will not be on the records we take. You don't have to take part in this study if you don't want to. If you decide later on that you don't want to take part in this study, you can leave the study if you tell us. No one will be mad at you. The way you receive care will not be different if you choose to not take part in the study.

This research has been approved by the following bodies: the Nepal Health Research Council and the University of California, San Francisco IRB. If you have any questions, please ask us. If you have any additional questions later, contact the Director of Implementation Research at Bayalpata Hospital or inform your CHW, who will be happy to answer them.

[Please ask for participant to explain the study, procedures, risks/benefits to confirm their understanding. Encourage questions and provide any additional explanations.]

Date: _____
Verbal Consent (circle one): YES NO

[Indicate in CommCare [form field X/Y] their consent to participate in research study.]