Version date: 14 August 2020

Acceptability and feasibility of Community-based mHealth Motivational Interviewing Tool for Depression (COMMIT-D) to improve adherence to treatment

Nyaya Health Nepal/Possible; University of California, San Francisco; Icahn School of Medicine at Mount Sinai

ClinicalTrials.gov NCT identifier: NCT04510909

INFORMED CONSENT - Patients

Investigators:

Bibhav Acharya, MD	Aradhana Thapa
Mental Health Advisor	Community Health Director
University of California, San Francisco	Nyaya Health Nepal
CONTACT: +977 986158502	CONTACT: +977 9851218352

Investigator's Statement

You are invited to participate in a research study conducted by the Ministry of Health and Population, Nyaya Health Nepal-Possible, the University of California, San Francisco, and the Icahn School of Medicine at Mount Sinai. We hope to learn more about how to improve treatment adherence for patients with depression 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 depression. You also are eligible as you live in the Nyaya Health Nepal catchment area population in Dolakha District. The research study is funded by the National Institutes of Health.

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:

- 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.
- Key-informant interview: you may be invited to attend an interview, one-on-one with a research staff member to assess acceptability (2 times) and feasibility (2 times). 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.
*All research procedures will take place in Dolakha, Nepal including at Charikot Primary Health Centre and/or in the community surrounding Charikot Primary Health Centre.

Risks and Benefits of the Study

You may not directly benefit from taking part in this study. You may not directly benefit from taking part in this study. However, we hope the results of the study will inform improvements to how CHWs deliver care for patients with depression in Dolakha and throughout Nepal, and thus improve patient care. We also hope the results of the study will inform improvements to how CHWs deliver care for patients with depression in Dolakha and throughout Nepal.

We will be developing a new mHealth application called COMMIT that will instruct CHWs with prompts to improve care for depression 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.

How will my information be used?
Researchers will use your information to conduct this study. Once the study is done using your information, we may share them with other researchers so they can use them for other studies in the future. We will not share your name or any other personal information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

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 family (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 (Charikot Primary Health Centre/CHWs in your community/Nyaya Health Nepal) 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.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

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, Nyaya Health Nepal at 9851031363 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; Icahn School of Medicine at Mount Sinai

ClinicalTrials.gov NCT identifier: NCT04510909

INFORMED CONSENT - CHWs

Investigators:

Bibhav Acharya, MD	Aradhana Thapa
Mental Health Advisor	Community Health Director
University of California, San Francisco	Nyaya Health Nepal
CONTACT: +977 986158502	CONTACT: +977 9851218352

Investigator's Statement

You are invited to participate in a research study conducted by the Ministry of Health and Population, Nyaya Health Nepal-Possible, the University of California, San Francisco, and the Icahn School of Medicine at Mount Sinai. We hope to learn more about how to improve treatment adherence for patients with depression by developing a mobile health application called COMMIT. You were selected as a possible participant in this study because you are a community health worker (CHW) employed by Nyaya Health Nepal, serving in Dolakha, and have been selected to receive motivational interviewing training. The research study is funded by the National Institutes of Health.

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 CHWs during the prototyping phase (1-2 times), acceptability testing phase (2 times), and feasibility testing phase (2 times). We will attempt to combine the acceptability and feasibility discussions. Each discussion 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.
*All research procedures will take place in Dolakha, Nepal including at Charikot Primary Health Centre and/or in the community surrounding Charikot Primary Health Centre.

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 depression in Dolakha 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.

How will my information be used?
Researchers will use your information to conduct this study. Once the study is done using your information, we may share them with other researchers so they can use them for other studies in the future. We will not share your name or any other personal information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

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 Population and/or Nyaya Health Nepal) 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.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

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, Nyaya Health Nepal at 9851031363 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: NCT04510909

INFORMED CONSENT – CHW Supervisors

Investigators:

Bibhav Acharya, MD	Aradhana Thapa
Mental Health Advisor	Community Health Director
University of California, San Francisco	Nyaya Health Nepal
CONTACT: +977 986158502	CONTACT: +977 9851218352

Investigator's Statement

You are invited to participate in a research study conducted by the Ministry of Health and Population, Nyaya Health Nepal, the University of California, San Francisco, and the Icahn School of Medicine at Mount Sinai. We hope to learn more about how to improve treatment adherence for patients with depression by developing a mobile health application called COMMIT. You were selected as a possible participant in this study because you supervise a community health worker (CHW) employed by Nyaya Health Nepal who has received training in motivational interviewing and who will use the COMMIT application. The research study is funded by the National Institutes of Health.

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 the pilot for feasibility testing (2 times). 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.
- Focus group discussion: you may be invited to attend a semi-structured focus group discussion with a research team member(s) and other CHW supervisors during the prototyping phase (1-2 times), acceptability phase (2 times), and feasibility phase (2 times). We will attempt to combine the acceptability and feasibility discussions for convenience. Each discussion will take ~30-60 minutes. Your answers will be recorded and the facilitator(s) will take field notes. *Research staff may contact you to clarify your responses.

*Research staff may contact you to clarify your responses.

*All research procedures will take place in Dolakha, Nepal including at Charikot Primary Health Centre and/or in the community surrounding Charikot Primary Health Centre.

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 depression in Dolakha 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.

How will my information be used?
Researchers will use your information to conduct this study. Once the study is done using your information, we may share them with other researchers so they can use them for other studies in the future. We will not share your name or any other personal information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

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:

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- 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:

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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.]