



Patient-Centered Stomach Cancer Prevention in Chinese Americans

August 2018

Agenda

Time	Session
9.30am-9.45am	Study Introduction
9.45am-10am	Good Clinical Practice
10am-1pm	Enrollment Study Procedures
1pm-1.45pm	Lunch
1.45pm-2.15pm	Health Education Sessions
2.15pm-3pm	Follow-Up Study Procedures
3-5pm	Motivational Interviewing and Goal Setting/Role Play

Stomach Cancer Risk Factors

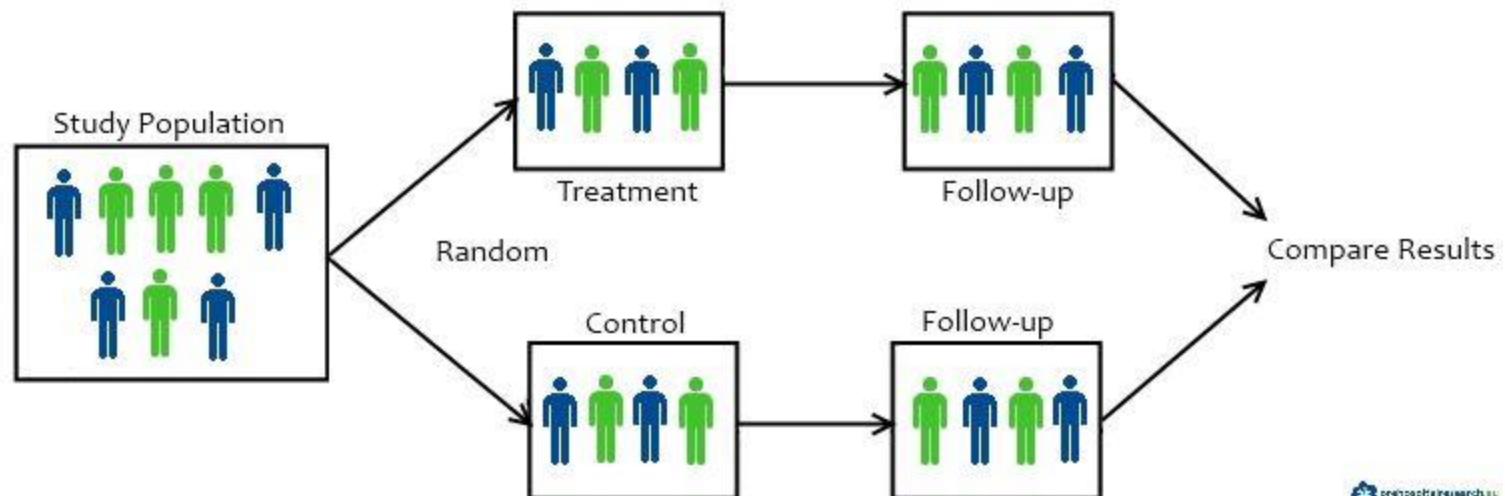
- H. Pylori infection
- Diet high in smoked foods, salted fish and meat, and pickled vegetables
- Lack of physical activity
- Smoking
- Drinking

Study Objective

- Assess the **efficacy, adoption, and impact** of an intervention to prevent stomach cancer in at-risk Chinese New Yorkers

Study Design

- Randomized controlled trial



Study Information

Eligibility criteria:

- Self-identifies as Chinese American
- Outpatient aged 21+
- Has a confirmed diagnosis of *H. pylori* infection

Recruitment will begin in August at the following sites:

- NYU Langone Hospital - Brooklyn (August 13)
- Seventh Avenue Family Health Center (August 15)
- NYU Langone Ambulatory Care – Bay Ridge (August 17)
- Bellevue Hospital (August 20)
- Gouverneur Hospital (tentatively August 20)

Study Total: 144 patients

Good Clinical Practice (GCP)

A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

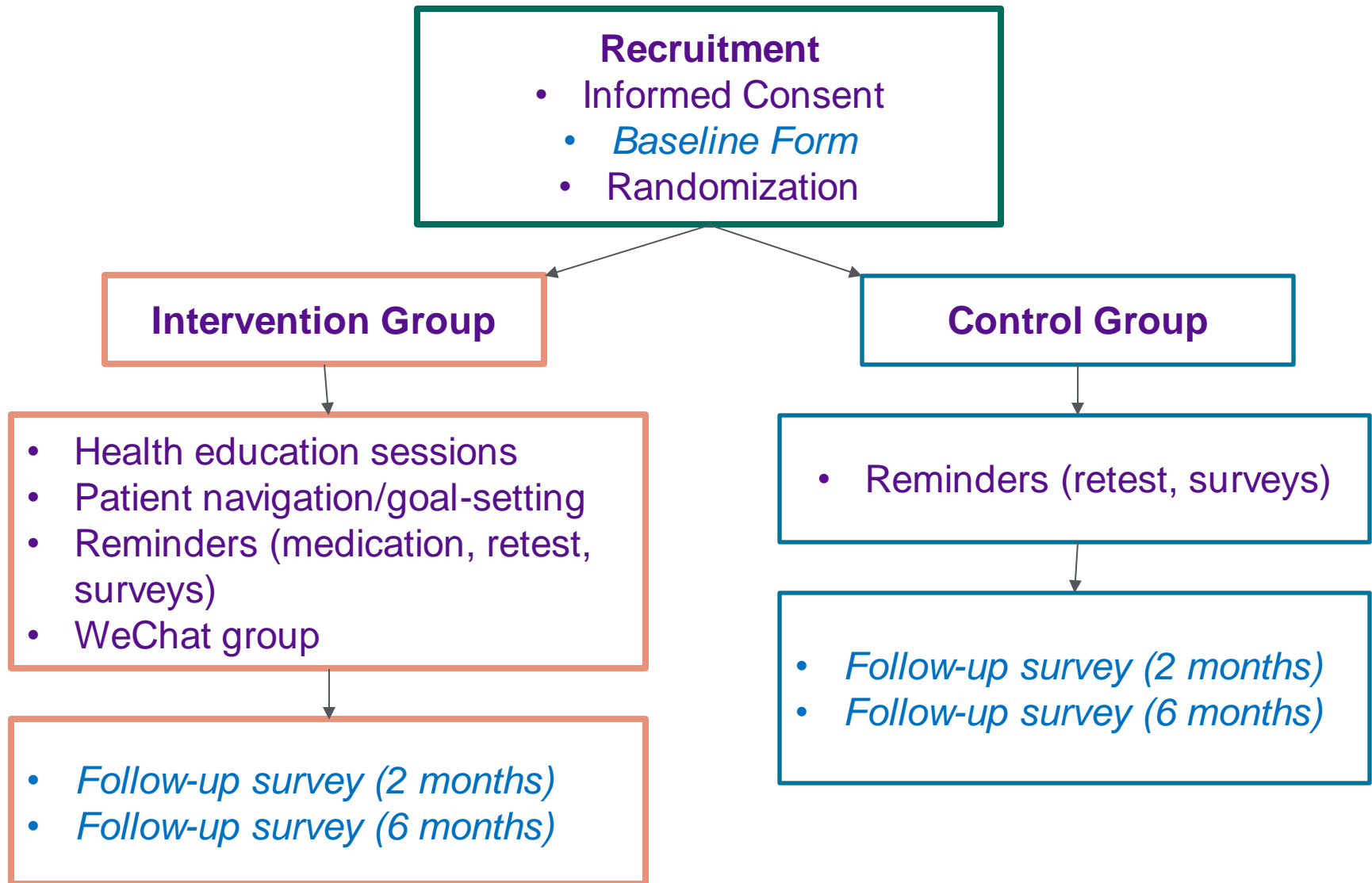
GCP Principles

1. Trials should be conducted ethically.
2. Benefits must justify the risks.
3. Rights, safety, and well-being of the trial subjects are the most important considerations and should prevail over interests of science and society.
4. Information on an investigational product should be adequate to support the trial.
5. Trials should be scientifically sound and described in a clear, detailed protocol.
6. Trial should have ethics committee approval.
7. Medical care given to subjects should be the responsibility of a qualified physician.
8. Study staff should be qualified.
9. Informed consent should be obtained from each subject.
10. Documentation should allow accurate reporting, interpretation and verification.
11. Confidentiality of records that could identify subjects should be protected.
12. Investigational products should be handled according to GMP and used only according to protocol.
13. Systems to assure the quality should be implemented.

STUDY PROCEDURES

Enrollment

Study Procedures



Referrals

Epic referrals

- Providers will copy Yi-Ling and Janet on eligible H. pylori-positive patients, who will track follow-up appointments
- Study sites: 7th Avenue FHC; NYU Langone-Brooklyn, NYU Langone Ambulatory Care Bay Ridge

Weekly list

- Providers will provide Yi-Ling and Janet with list of eligible patients and their appointments
- Study sites: Gouverneur Hospital, Bellevue Hospital

TO BRING TO RECRUITMENT VISIT

- RECRUITMENT MATERIALS
 - 2 copies of informed consents per patient
 - Baseline survey
 - Randomization envelope (with correct UID: check Subject Log prior to going to the clinic)
 - Patient health education materials
 - Encounter Log/Report
- Fully charged work phone (with WeChat)
- Survey tool (scales)
- NYU Badge
- Pen and clipboard
- \$25 gift card and gift card receipt

SUBJECT LOG: ASSIGNING SUBJECT UID



SUBJECT LOG

SUBJECT ID	DATE ENROLLED	SUBJECT NAME	GROUP (Control/Intervention)
001	15 Aug 2018	Lǐ Měiměi	Control
002	18 Aug 2018	Chen Zhang	Intervention
003	30 Aug 2018	Zhao Kang	Intervention
004			
005			

ALWAYS CHECK THE SUBJECT LOG IN THE STUDY BINDER FOR NEXT SUBJECT UID!

Screening

- Arrive at time of patient appointment
- **Connect with the receptionist/doctor**
- Move to quiet space
- Give information about the study and answer questions
 - Randomized study
 - Patient may be in control or intervention group: cannot choose which group he/she is in
- Let patient know that you might need approximately one and a half hour of his/her time

Suggested Recruitment Script

CHW: “Hello! My name is [CHW NAME] and I am a community health worker working with NYU Langone Health and [name of clinic, name of doctor] to talk about a health education study that can help eligible patients manage their H. pylori treatment and reduce their risk of stomach cancer. We are also working on this at 4 other health centers. Would you be interested in hearing more about this study?”

Key Messages

- H pylori is linked to stomach cancer, and stomach cancer disproportionately affects Chinese people in NYC.
- This study is important because there is very little data and research about the Chinese community, and we do not know very much about the best strategies to help Chinese people prevent stomach cancer. Your participation will come at no medical risk to you and will help benefit the Chinese community.
- The only potential risk to participating in this study may be potential loss of privacy – however, every effort will be made to keep your answers confidential.
- Participation is voluntary and will not affect your relationship with your doctor

Suggested Recruitment Script

Description of Study

- This study is about ways to prevent stomach cancer in the Chinese community in NYC. The design of the study is such that approximately half the people will be chosen to have a CHW assigned to them and receive health education over 6 months; and the other half will receive some simple health education materials. You cannot choose which group you are in – the computer randomly assigns your group. It is like rolling dice to decide which group you may be in.
- If you are in the CHW group, you will be enrolled in a free program to receive health education sessions by your assigned CHW on H. pylori and ways to prevent stomach cancer. Your CHW will set up a time to meet you to give those sessions. There are 2 main sessions but they can be broken up into smaller topics. You will also receive phone calls from your CHW every month to chat about your health.
- If you are in the health materials group, we will give you some health materials about H. pylori and stomach cancer.
- For everyone, we will also fill out a questionnaire on the first day, at 2 months, and at 6 months.
- Every time you finish a questionnaire, we will give you a \$25 gift card. Since there are 3 times we will be filling out a questionnaire, you will receive \$75 in gift cards by the end of the study.
- If you are interested, I will need approximately one and a half hours of your time to fill out the consent form, and to complete the first questionnaire.

Recommendations

- Doctor-recommended
- Working at 4 other NYU clinics
- Flexible – can work around your schedule
- Doctor has limited time; we can help you
- Help people in the Chinese community understand H pylori and stomach cancer (very little data)
- If you're not doing it for yourself, do it for your family

ENROLLMENT

Informed Consent Form (ICF)

- Patient should understand study procedures
- No data can be collected from the patient until he/she gives consent
- Patient must sign and date two copies of the ICF
- CHW must sign and date the ICFs
- Assign Subject UID (3 digit number) and write UID on top right corner of ICF

REVIEW ICF HERE

PARTICIPANT CONTACT INFORMATION

- Record as many ways of contact as possible: address, various telephone numbers, email address
- Verify phone number
- Add to WeChat if participant is willing (as individual)
- Record preferred method of contact and best days/times to contact
- Ask participant to inform you if h/she changes contact information

CHW Contact Information

- Give them your work desk phone number and the iPhone number
- Do not give them your personal number

ENROLLMENT

If the participant does not have much time:

- Review and sign ICF
- Get participant contact information
- Arrange for another time (within 1-5 days) when you can administer the baseline survey and possibly the first health education session in-person
- Do not assign Subject UID for now

BASELINE SURVEY

- All questions on the baseline survey should be collected:
 - In person
 - On the day of enrollment
- Fill out the Subject UID on the top of every page
- Write legibly in black or blue ink
- Follow survey instructions (*ie. Read all options vs Do not read options*)
- Do not skip questions unless instructed to
- If patient does not want to answer questions, check or write in “**refused**” so we know that you did not miss the question
- If you make a mistake, cross out the wrong response, and write your initials and date next to it

SL 8/16/18 ~~☒~~ Less than \$25,000

REVIEW/ROLE PLAY BASELINE SURVEY

RANDOMIZATION

Before opening a randomization envelope for the patient, check that:

- He/she has signed the ICF
- He/she is fully eligible for the study
- The baseline survey has been completed
- Check that the UID on the envelope corresponds to the UID assigned to the patient

As soon as the envelope is opened, the patient is considered enrolled in the study

- Check that the UID on the randomization card matches the UID on the envelope
- Record the patient's group in the baseline survey
- **DO NOT THROW RANDOMIZATION CARD AWAY:** Staple to baseline form

RANDOMIZATION ENVELOPES



Blue card = Control Group



Yellow card = Intervention Group

POST RANDOMIZATION

Explain to the patient which group he/she has been assigned to:

CONTROL GROUP

- Give patient health education materials
- Encourage the patient to follow the doctor's orders for the medication, but do not provide additional information
- Remind patient to do a confirmatory test 6-8 weeks after completing the medication
- Schedule tentative follow-up interview date for 2 month survey

INTERVENTION GROUP

- Give patient health education materials
- Encourage patient to fulfill prescription; if necessary, accompany him/her to the pharmacist
- Together with the patient, discuss strategies to take the medicines on time. Set up schedule for reminder calls/texts.
- Discuss medication side effects
- Schedule follow-up appointment for Session 1 within the week.
- Tentatively schedule rest of the health education sessions.

Compensation

- Provide the participant with \$25 gift card
 - ✓ Hong Kong Supermarket gift card (Manhattan)
 - ✓ iFresh/New York Supermarket gift card
- Complete Gift Card Receipt
 - ✓ Document date and amount
 - ✓ Participant signature
 - ✓ CHW signature/initials

NON-ENROLLMENT

- If you meet with the participant and he/she decides not to enroll or is ineligible, document this in the Not Enrolled Log in the Regulatory Binder



NOT ENROLLED LOG

Date	Initials	Study Site	Reason for Non-Enrollment
16 Aug 2018	ZH	7th Ave FHC	Not interested
20 Aug 2018	YS	Belleme	under 21 years old

INTERVENTION GROUP

Health Education Sessions and 6-Month Follow-Up

OVERVIEW: H Pylori and Stomach Cancer

CONTENT

- What is H. pylori
- Symptoms
- Transmission
- Complications (risk factor for stomach cancer)
- Treatment and factors affecting treatment success

KEY MESSAGES

- Side effects
- Importance of treatment adherence

STRATEGIES

- Reminders/alerts
- Ways to alleviate side effects
- Encouragement and support

OVERVIEW: HEALTHY EATING

CONTENT

- Link between diet and stomach cancer
- Types of food that may cause stomach cancer
- Healthy eating: what a healthy plate looks like
- Strategies for healthy eating
- Addressing barriers to healthy eating

KEY MESSAGES

- Reduce salt, preserved vegetables, and processed food
- Eat more fresh vegetables and fruits
- Read food labels

STRATEGIES

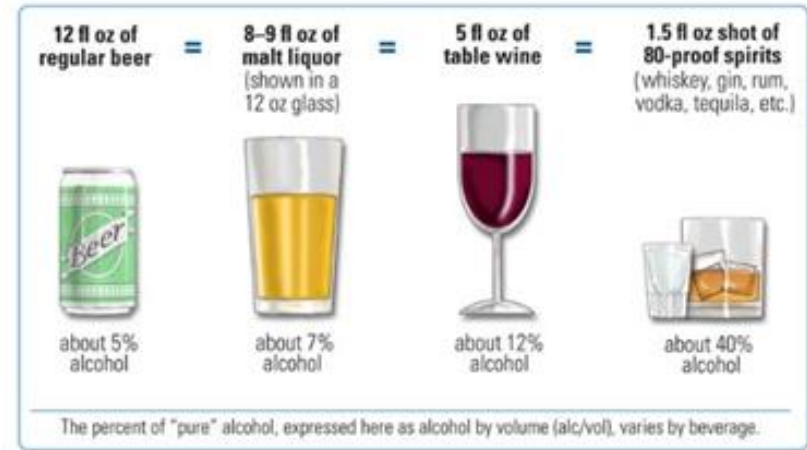
- Goal-setting

Nutrition Facts	
8 servings per container	
Serving size	2/3 cup (55g)
Amount per serving	
Calories	230
% Daily Value*	
Total Fat 8g	10%
Saturated Fat 1g	5%
Trans Fat 0g	
Cholesterol 0mg	0%
Sodium 160mg	7%
Total Carbohydrate 37g	13%
Dietary Fiber 4g	14%
Total Sugars 12g	
Includes 10g Added Sugars	20%
Protein 3g	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 8mg	45%
Potassium 235mg	6%
* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.	

OVERVIEW: ALCOHOL REDUCTION

CONTENT

- Link between alcohol and stomach cancer
- Definition of one standard drink
- Definition of heavy and moderate drinking
- Strategies for reducing alcohol consumption
- Barriers to reducing alcohol consumption



KEY MESSAGES

- Be aware of how much you are actually drinking

STRATEGIES

- Goal-setting
- Referral to resources

OVERVIEW: PHYSICAL ACTIVITY

CONTENT

- Link between obesity, lack of physical activity, and stomach cancer
- Recommended physical activity guidelines
- Strategies for increasing physical activity
- Barriers to increasing physical activity

KEY MESSAGES

- Do at least 30 minutes of moderate activity 5 days/week

STRATEGIES

- Goal-setting
- List of resources

OVERVIEW: SMOKING CESSATION

CONTENT

- Link between smoking and stomach cancer, as well as other cancers and health problems

KEY MESSAGES

- No safe amount of smoking
- Second-hand smoke is harmful to people around you
- Once you quit, the benefits are almost immediate
- Do not be discouraged because you have previously failed to quit

STRATEGIES

- Goal-setting
- Referral to Asian Smokers Quitline (*bring web referral form with you*)

TIMELINE OF SESSIONS

From Day 0 (enrollment) to 1 week

- H. pylori and stomach cancer session (can be with family)
- Reminder texts/calls

From 1 week to 4 weeks

- Healthy Eating
- Alcohol Reduction
- Physical Activity
- Smoking Cessation

- *Can be done in 2-4 sessions*
- *Depends on participant schedule*
- *Space them approx. 1 week apart*

Sample Plan

H Pylori and Stomach Cancer: *Day 2*

Healthy Eating: *Day 10*

Alcohol Reduction: *Day 18*

Physical Activity: *Day 18*

Smoking Cessation: *Day 25*

CHECK-INS

Continue checking in with intervention group subjects after the health education sessions are over

- Reminder(s) for confirmatory retest 4 to 6 weeks after end of medications
- WeChat group sessions (only for intervention group)
- **Monthly phone check-ins on goals outlined in goal-setting sessions between Month 2 to 6**

ENCOUNTER LOG

STOMACH CANCER PREVENTION STUDY	Enrollment date	20 August 2018
ENCOUNTER LOG	H. Pylori Session	21 August 2018
	Healthy Eating Session	26 August 2018
Participant UID: 008	Alcohol Reduction Session	26 August 2018
Randomized Group: Control / Intervention	Physical Activity Session	
	Smoking Cessation Session	
	Re-test	
	2-month Follow-Up Survey	
	6-month Follow-Up Survey	

Date / Time	CHW Initials	Encounter Type	Outcome Code	Comments/ Explanation
8/21/18	SL	OO	SP	H Pylori session at patient's home
8/23/18	SL	PC	SP	Reminder phone call to take medicine
8/26/18	SL	OO	SP	Did 2 educational sessions
8/30/18	SL	PC	AM	Reminder call / left a message

ENCOUNTER TYPE:

PHONE CALL (PC)
ONE-ON-ONE (OO)
OTHER (Explain)

OUTCOME CODES:

SP= Spoke with participant (explain)
AM= Left message on answering machine or voicemail
CC= Phone call from client (explain)

LM= Left message with person who answered the phone
NA= No Answer
OT= Other (explain)

STOMACH CANCER PREVENTION STUDY ENCOUNTER REPORT

PARTICIPANT UID: 008

CHW Name: Stephanie Liu

Encounter Date: 8/26/18

Encounter Time: 4pm

Encounter Type: In Person or Phone Call? In-person

Describe what occurred or what was discussed. (Called to remind patient to take medication; Completed Session 1 of H. pylori education, etc)

Completed sessions on healthy eating and physical activity.

Describe any problems/challenges faced by participant, if applicable. (Strong side effects of medication, too busy to exercise, etc)

He works in a restaurant and did not think he can eat healthier, since he cannot choose his food. He also has no time to exercise.

Describe the actions taken or recommendations provided by the CHW (Medication reminder strategies; referrals to ASQ, etc)

I encouraged him to choose smaller portions, put less salt on his food, and choose more vegetables. I also encouraged him to do some strength training exercises.

Describe the outcome (Goals set, etc)

He set a goal of borrowing his colleague's weights and exercising with them 2x/week.

FOLLOW-UP REQUIRED

Describe any necessary follow-up or any follow-up that was provided

Will complete session on smoking on 8/29.

Goal-Setting

DEVELOPMENT OF SHORT-TERM ACTION PLAN

- ☐ Eat a healthy diet
- ☐ Be physically active
- ☒ Quit or reduce smoking or alcohol: Quit or reduce to: 5 drinks per [circle one:] day / week
- ☐ Other (describe)

Record of Participant Plan:

What I will do (e.g. go for a 15 minute walk): Limit myself to 1 drink per occasion

When I will do it (e.g. in the morning after breakfast): Every time I have dinner

Where I will do it (e.g. around the block): When I am having dinner outside

How often I will do it (e.g. M, W, F): Every time I have dinner

What might get in the way of my plan (e.g. too cold outside): My friends will make me drink

What I can do about it (e.g. use the treadmill in the community center): I will tell them that I am trying to be healthier and prevent stomach cancer.

Participant's Confidence Level in Reaching Goal: 7

[fill in the number that participant selected, 0 (not at all) – 10 (totally confident)]

[Note: Use Brief Action Planning Guide to revise Participant Plan until confidence is greater than 7.]

CONTROL GROUP

6-Month Follow-Up

CONTROL GROUP CONTACT

Limited contact:

- Reminder to retest (4-6 weeks after enrollment)
- Scheduling of 2 and 6 month surveys
- Reminders about surveys
- Complete Encounter Log after every participant contact

FOLLOW-UP SURVEYS

Intervention and Control Groups

FIRST FOLLOW-UP SURVEY

- To be completed at 2 months after enrollment
- Try to schedule/complete it after subject has obtained results of confirmatory test
- Send reminder a few days before appointment
- Give/mail \$25 gift card after completion of survey

SECOND FOLLOW-UP SURVEY

- To be completed at 6 months after enrollment
- Send reminder a few days before appointment
- Ask about confirmatory test results if not obtained at 2 month follow-up survey
- To be completed by different interviewer (only for intervention group)
- Give \$25 gift card after completion of survey (and CHW section for intervention group)

ROLE PLAY THE FOLLOW-UP SURVEY

LOST TO FOLLOW-UP

- Document all attempts to contact the subject on Encounter Log
- Call at least once a month for 6 months

HOME VISIT PROTOCOL

- Refer to Home Visit Guide
- Email Yi-Ling/Janet the participant's name and address, and date/time of interview
- Inform Yi-Ling/Janet when you arrive and depart from the participant's home
- Do not conduct the interview if you do not feel safe for any reason

Motivational Interviewing

Traditional Approach

Client: I live with 5 other people in a small apartment and we share a kitchen. It is always crowded and I don't feel like cooking on my day off, since I work in a restaurant. I'm trying to save money to pay off my debt, so I just buy something something cheap or I eat instant noodles.

What would you say?

SUMMARY

1. Set the agenda together
2. Explore feelings about change
3. Ask-Tell-Ask
4. Assess readiness to change
5. Set SMART goal together
6. Summarize and express confidence

Set the Agenda Together

- Open the conversation – Ask Permission
 - Can you tell me what you know about stomach cancer and how to prevent it?
 - Would it be ok to talk about healthy eating and strategies to avoid stomach cancer?
 - Would you be interested in exploring with me some of the ways you might prevent stomach cancer?
 - Which of these do you feel more ready to think about changing? (quitting smoking, physically active, eating healthy, etc)
- Ask about how participant is incorporating healthy strategies into their life
- Ask if they have any nutrition/health concerns they want to focus on
- Go over key messages

Key Messages

- Keep the key messages short; repeat often
- Ask for their reactions/thoughts.
 - How do you feel about what I've just shared with you?
 - How much does it concern you?
 - Tell me about things you want to be different.
 - What are your thoughts on how you are managing your health?
- Intention to change
 - If you could easily make any changes, what would you do?
 - Nevermind the “how” for now, what do you want to happen?
 - How important is this to you?

Explore Feelings about Change

- Listen and reflect/summarize their feelings about change
- Preliminary assessment of readiness to change
 - “You said that exercising more is something that you were interested in doing... how ready are you to make changes?” “How do you feel about quitting smoking?”

Types of Reactions

- Not interested in changing any behavior
 - I sense you aren't ready to work on this right now. That's fine. It's ok to feel two ways about this.
 - I agree, there's no point in trying something that's not going to work.
- Be willing to change a behavior
- Be ambivalent about changing a behavior

Ambivalence

- Focus on the participant's "change talk"
- Desire to change / Ability to change / Reason to change / Need to change / Commitment to change / Activation / Taking steps
- Allow him/her to make own argument for change – use their words

"I really don't know if this will work, but maybe I should try."

- How would you reflect?

Ask-Tell-Ask

- “There is usually more than one possible course of action.”
- “I can tell you what’s worked for some other people.”
- “You are the best judge of what works best for you.”
- “Let’s go through some of the strategies together.”
- “I have some ideas about how you could..... Would you like to hear about them now? What ideas can you suggest?”

When the participant sets a goal/strategy, let him/her know that they can adjust the strategy based on what is and is not working. For some people, gradual changes work better.

- Ask them what they’d like to do or what they think of the information you provided
- “If you did decide to make this change, what might you do to succeed?”

Set SMART Goal

- Specific
- Measurable
- Achievable
- Realistic
- Timely

Assess readiness to change

Use the Confidence Ruler to assess readiness to change

- “What would you like to focus on changing?”
- “How confident are you that you will be able to make this change, on a scale from 0 to 10?”
- If the answer is lower than 6, ask “what can you change to make it possible to raise your number to 7?”
 - Make the goal more realistic: less ambitious
 - Enlist social support (family/friends)
- Elicit reasons for change and summarize them

Goal Setting

- Ziyi has no children and is not married, though she has a boyfriend.
- Ziyi tells you that she is very busy at work and does not have time to cook, so she eats whatever is provided at work, which is mostly rice, noodles, and some meat and vegetables. She loves pickled vegetables and pizza.
- She also tells you that she is thin, so she does not feel the need to exercise.
- Ziyi says that she is constantly stressed at work, so she smokes one or two cigarettes a day. Her coworkers also expect her to go on smoking breaks with them.
- Ziyi also drinks almost every night, since she has to entertain clients for work during dinner.



Goal Setting



- Tony has 3 children and is married.
- Tony works 12 hours/day at a store. His only day off is Monday.
- He usually skips breakfast and his wife packs his lunch. For dinner he usually grabs fast food.
- He does not have any time to exercise.
- He smokes one pack of cigarettes a day, and drinks occasionally.

Goal Setting

- Jet is married and has 4 children in China.
- Jet works at a restaurant 6 days/week.
- He skips breakfasts but eats lunch and dinner at the restaurant where he works. On his days off, he eats the cheapest food he can find because he is saving money to send home to his family.
- He does not smoke and drink.
- He enjoys practicing wushu but does not have much time for it.



Potential Participant 001

Name: Ye Yi Shuai

Age: 42 yo

Address: 660 57th St, Apt 1, Brooklyn

Phone: 646-662-6908

Emergency contact: Lin Shan Yong (friend); 917-855-1378

Preferred pharmacy: A Plus Pharmacy, 5605 7th Ave, Brooklyn

Diagnosis: H pylori and gastritis

Smoking history: Heavy tobacco smoker, 1ppd (20 years)

Drinking history: 5.4oz alcohol/week (alcohol abuse, continuous)

Married

Pilot Study Results

Causes of H pylori

- H pylori infection
- “Beige eating”
- Spicy food
- Seafood/BBQ
- Staying up late
- Ageing
- Unhygienic conditions

Pilot Study Results

Causes of stomach cancer

- H pylori infection
- Spicy food
- Fatty meat
- Irregular food
- Smoking
- Drinking

Pilot Study Results

Do you think you are at risk for stomach cancer?

- No/Don't think so/Not really: 6 (86%)

"I eat a lot of seafood and fish..."

"I believe that god will arrange everything. I'll just go with it."

"I am in good condition, never feel ill, and I finished my treatment already."

"I think everyone is at risk but as long as you're compliant with your medication, you should be fine."

Question: How do you respond to this as a CHW?

Pilot Study Results

How to prevent stomach cancer

- ✓ Eat healthy
 - Eat less seafood
 - Eat less spicy food
 - Put less salt in vegetables
 - Eat every meal on schedule
- ✓ Drink less alcohol
- ✓ Smoke less
- ✓ Sleep early/rest more
- ✓ Regular visits to doctor

Pilot Study Results

Barriers to attending sessions

“I work 6 days a week and have only 1 day off. When I am at home rest, I need to do cleaning and many other stuff. Working is really intense and busy, my boss doesn’t allow us to look at our phones, so I need to hide in a bathroom to take calls.”

“It would be better if the CHW can contact me after 11pm, because I work late and I don’t have time to talk on phone during day time.”

“Talking by phone or in person are both work for me, I don’t feel much different.”

Experience with CHW

“She was very caring and reminded me what I should pay attention to for my health. Overall it was a very good experience...All the interviews and sessions were just like chatting with a friend.”

“Stephanie is a nice person, she helped me with my appointments and stuff when I tell her that I need to see a doctor.”

“Stephanie is good, she’s really kind. She teaches me a lot about H pylori infection.”