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Research on the construction and effect evaluation of health literacy intervention measures for Yi nationality residents in Liangshan Prefecture

Submission date 26/05/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 01/06/2022	**Overall study status** Completed	
Last Edited 15/08/2022	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Improving urban and rural residents' health literacy helps to improve their ability to identify and solve their own health problems. It is an important strategy and measure to improve people's health and one of the main indicators of the Healthy China 2030 Plan. However, at present, the health literacy level of Residents in Liangshan Yi Autonomous Prefecture is still at a low level (only 11.62%), and the health literacy level of residents in some Yi autonomous counties is only about 1%. Improving the health literacy of the Yi nationality residents is a key issue to be urgently solved. The main aim of this study is to propose a set of health literacy interventions for Yi nationality residents in Liangshan Yi Autonomous Prefecture and improve the health literacy of local residents. This study also hopes to propose a set of electronic questionnaire quality control systems and artificial intelligence-based quality control methods to provide a tool reference for future field interventions and investigations in underdeveloped areas.

Who can participate?
Yi residents aged 15-64 years old who have lived in Meigu County and Yanyuan County of Liangshan Yi Autonomous Prefecture for more than half a year, whose native place is Liangshan Yi Autonomous Prefecture

What does the study involve?
Interventions are proposed to include key steps such as project preparation, core mobilization, internal radiation and competitive incentives, with Contracted Family Doctor Services as a comparison. Project preparation refers to organizing experts and responsible persons of health education and chronic non-communicable disease prevention to establish advisory committees, providing health knowledge support, health skills support, information technology support, financial support, etc for the sponsors of each family branch. Core mobilization refers to the recruitment, screening and training of various sponsors. Internal radiation refers to health literacy education, including nutrition education, carried out by the sponsor of each branch to other members of the branch using health literacy pamphlets in accordance with the operation

manual. Finally, to inspect and test the actual mastery of health literacy in the subjects, the traditional Yi festival activities such as "Sai Shuo" are used to carry out health literacy knowledge competitions in families and branches on a regular basis. The residents' health literacy level in the Healthy Liangshan Performance Evaluation Index is taken as the main outcome. Questionnaires and physical examination information will be collected at the 1st, 3rd, 6th, 9th and 12th months.

What are the possible benefits and risks of participating?
Residents participating in the study can improve their health literacy through the interventions. However, since the study will last for a long time, there may be a risk of disclosure of personal information. In view of this, the researchers will use strict data management measures. They will not collect individually identifiable data and will replace it with numbers to reduce the risk of disclosure, so there will be no risk to residents’ privacy.

Where is the study run from?
West China School of Public Health and West China Fourth Hospital, Sichuan University (China)

When is the study starting and how long is it expected to run for?
January 2020 to May 2023

Who is funding the study?
1. National Natural Science Foundation of China (China)
2. Chongqing Science and Technology Program (China)
3. Liangshan Community Diagnosis Project (China)

Who is the main contact?
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Additional identifiers

Study information

Scientific Title
Study on the construction and effect evaluation of health literacy intervention measures for Yi nationality residents in Liangshan Prefecture based on the joint model of "Contracted Family Doctor Services + Family Branch System": research of stepped-wedge cluster randomized controlled trial

Study objectives
Study objectives:
1. Based on the traditional ICCC framework and the unique Family Branch System of Liangshan Yi Autonomous Prefecture, propose a set of health literacy interventions for the Yi nationality residents in Liangshan Yi Autonomous Prefecture to improve the health literacy of local residents.
2. Propose a set of electronic questionnaire quality control system construction and artificial intelligence-based quality control method to provide a tool reference for future field intervention and investigation in underdeveloped areas.
3. Improve the statistical analysis method of stepped-wedge design, and propose a hybrid model-based main hierarchical causal inference method to solve the common non-compliance problems in the stepped-wedge design, which will not only improve the accuracy of the intervention effect evaluation, but also promote the development of statistical methodology for stepped-wedge studies.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/05/2022, Ethics Committee of West China Fourth Hospital and West China School of Public Health, Sichuan University (No. 16, section 3, Renmin South Road, Wuhou District, Chengdu, Sichuan, China; +86 (0)28 85508845; hxgwsylunli@163.com), ref: Gwll2022068

Primary study design
Interventional

Study design
Stepped-wedge cluster randomized trial using an open cohort design

Study type(s)

Prevention

Health condition(s) or problem(s) studied
Residents’ health literacy

Interventions
Taking residents aged 15-64 years in Liangshan Yi Autonomous Prefecture as the research object, based on the joint model of "Contracted Family Doctor Services + Family Branch System", members of family branches are recruited as the intervention group for the health literacy intervention, and the routine "Contracted Family Doctor Services" in Liangshan Yi Autonomous Prefecture are used as the control measure. Meigu County and Yanyuan County of Liangshan Yi Autonomous Prefecture carry out various forms of health education activities for residents' health literacy every year, and this study will appropriately enrich health literacy promotion programs in normal management work. In addition, the study areas have inconvenient transportation, low overall education level and relatively closed information. Therefore, it is difficult for subjects to perceive the transition from the non-intervention state to the intervention state, which ensures the implementation of a blinded method for subjects to some extent.

The designed interventions are intended to include key steps such as project preparation, core mobilization, internal radiation and competitive incentives. Project preparation refers to organizing experts and responsible persons of health education and chronic non-communicable disease prevention to establish advisory committees, providing health knowledge support, health skills support, information technology support, financial support, etc for the sponsors of each family branch. Core mobilization refers to the recruitment, screening and training of various sponsors. Internal radiation refers to health literacy education, including nutrition education, carried out by the sponsor of each branch to other members of the branch using health literacy pamphlets in accordance with the operation manual. Finally, to inspect and test the actual mastery of health literacy in the subjects, the traditional Yi festival activities such as "Sai Shuo" are used to carry out health literacy knowledge competitions in families and branches on a regular basis.

R 4.0.5 is used to generate random numbers, and a unique number will be assigned to the family branches recruited in Meigu county and Yanyuan County respectively to generate sampling framework. Using simple random sampling, six branches are selected from Meigu county and Yanyuan County respectively, and divided into four groups by independent complete randomization. In the next stage, 50 random samples of eligible individuals will be selected in each branch according to gender and age stratification, and the sampling work will be carried out by statistical members of the research group. The intervention will be initiated 3 months after the start of the trial in groups 1 and 2, and 6 months after the start of the trial in groups 3 and 4. The study period is 1 year, from May 2022 to May 2023, with follow-up for the last 3 months.

Intervention Type
Other

Primary outcome(s)
Health literacy of residents measured using the 2020 Residents Health Literacy Monitoring Questionnaire at the 1st, 3rd, 6th, 9th and 12th months of the experiment

Key secondary outcome(s)

Measured at the 1st, 3rd, 6th, 9th and 12th months of the experiment:
1. Smoking and drinking status of the residents measured by questionnaire
2. Height and weight measured using a height and weight measurement instrument
3. Blood pressure measured using a blood pressure meter
4. Blood sugar measured by venous blood drawing

Completion date
25/05/2023

Eligibility

Key inclusion criteria
1. Native place is Liangshan Yi Autonomous Prefecture
2. Have lived in Meigu County or Yanyuan County of Liangshan Yi Autonomous Prefecture for more than half a year
3. Yi nationality residents living in compact communities aged 15-64 years
4. Voluntarily participate in the project

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Key exclusion criteria
1. Pregnant women
2. People with serious disabilities who cannot be examined
3. Mental patients

Date of first enrolment
01/06/2022

Date of final enrolment
26/02/2023

Locations

Countries of recruitment
China

Study participating centre

Yanyuan County Center for Disease Control and Prevention
Liangshan Yi Autonomous Prefecture
China
615700

Sponsor information

Organisation
National Natural Science Foundation of China

ROR
https://ror.org/01h0zpd94

Organisation
Chongqing Science and Technology Program

Organisation
Liangshan Prefecture Center for Disease Control and Prevention

Funder(s)

Funder type
Government

Funder Name
National Natural Science Foundation of China (grant number 81602935)

Alternative Name(s)
Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhuì, , NSFC, NNSF, NNSFC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Funder Name
Chongqing Science and Technology Program (grant number cstc2020jscx-cylhX0003)

Funder Name
Liangshan Community Diagnosis Project (grant number H210322)

Results and Publications

Individual participant data (IPD) sharing plan

The datasets analyzed during the current study will be available from Tao Zhang (statzhangtao@scu.edu.cn) on reasonable request. Upon reasonable request by other researchers, raw data (Excel file) will be made available after the publication of the scientific reports and with the agreement of all program board members. Data can be used for scientific peer-review or meta-analytic procedures. Data will be collected with participants' informed consent and would be fully anonymised.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		13/08/2022	15/08/2022	Yes	No